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INTRODUCTION

The Military Interoperable Digital Hospital Testbed (MIDHT) is a five-year program of research to develop a real-world testbed environment in Southwestern Pennsylvania. The purpose is to research and evaluate Health Information Exchange (HIE) and health information technology (HIT) and services that make health information readily available to consumers and providers. Ideally this will allow for the secure transfer of information between private sector rural providers, federal partners and patients. MIDHT has defined requirements and solutions to optimize healthcare resources for rural communities and identified lessons learned and best practices that benefit both the global Military Health System (MHS) environment and stakeholders in the region. The Department of Defense (DoD) and Conemaugh Memorial Medical Center (CMMC) have common requirements for HIE, connecting disparate systems and providers and enabling secure provider-provider and provider-consumer e-communications. Minimal evidence is available on what business, clinical and technical solutions can be used to overcome the lack of specialists, infrastructure and geographical barriers associated with the delivery of care in rural communities.

BODY

Arm 1: Longitudinal Study for Use of Interoperable Accessible Health Information Exchange Services and Technologies in Rural Communities (A – 15835.2, A – 16192.1).

This arm focused on ways a rural environment can capitalize on the use of health information network (HIN) services and technologies to promote interoperability between disparate entities such as TRICARE providers, private sector health systems, and DoD facilities. MIDHT investigated attitudes, usability, and effectiveness of HIN services by rural providers, including the effect of the use of HIE tools by provider groups, TRICARE providers, and three CHS facilities on their business practices and process flows. Research initiatives focused on the impact of an electronic health record (EHR) implementation using instruments utilized in year 1. Additionally, research initiatives evaluated the ability to electronically access digital radiology images and how this system-wide functionality affected the delivery of patient care within a rural health care system, to include an analysis on provider productivity, throughput, duplicative testing and continuity of care. Finally, an assessment of the volume of cases that Conemaugh physicians have with the Social Security Administration (SSA) regarding veteran/military disability claims was completed through a provider satisfaction survey regarding the existing SSA process.

Subtask 1.1 Assess changes in provider workflows and efficiency resulting from the implementation of an ambulatory electronic medical record.

Study A-15835.2

Respective protocol received Conemaugh administrative, scientific and IRB approvals during the third quarter of Funding Year 1. USAMRMC IRB approval was granted on May 18, 2010, allowing Conemaugh to begin study implementation. Distribution of EHR surveys to staff/physicians and comprehensive workflow shadowing of staff/physicians at both locations began in June 2010 as the EHR stabilization period (3 months) ended per protocol design.

After the implementation of an EHR and a three-month stabilization period, 19 providers between the Portage and NORCAM ambulatory facilities (Table 1) were each shadowed for a continuous four-hour time period. Researchers used the Time and Motion Study Tool: Ambulatory Practice (TMS-AP) developed by Partners HealthCare, in order to be consistent with previous completed work. The new data set ("POST") from 2010 allowed for a statistical comparison to the "PRE" data set collected in 2008.

Location	Subject	Date
Portage	Clerical	6/14/2010
Portage	Clinical	6/14/2010
Portage	Physician	6/14/2010
NORCAM	Clinical	6/21/2010
NORCAM	Physician	6/21/2010
NORCAM	Clerical	6/21/2010
Portage	Clinical	6/28/2010
Portage	Clerical	6/28/2010
Portage	Physician	6/28/2010
NORCAM	Physician	6/30/2010
NORCAM	Clerical	6/30/2010
NORCAM	Clinical	6/30/2010
Portage	Physician	7/7/2010
Portage	Office Manager	7/7/2010
Portage	Clerical	7/7/2010
NORCAM	Office Manager	7/19/2010
NORCAM	Clerical	7/19/2010
Portage	Clinical	8/13/2010
Portage	Physician's Assistant	11/4/2010

Table 1. EHR POST Observations Schedule

The following section describes the statistical analysis completed when comparing the PRE and POST workflow data sets.

[Mann-Whitney Test (MWT) with Alpha = 0.05 was used for all significance testing. Note, MWT utilizes ranks and not means.]

The variable, percent of time period total time, was calculated independently for each time period (PRE and POST) using the same procedure; namely, the time for each observed activity was normalized by dividing it by the total time of the period in which it was recorded and then multiplying the dividend by 100. This mitigates the difference in total time between time periods and allows for more accurate, interpretable, and directly comparable results between time periods. For readability, the variable, percent of time period total time, will henceforth be denoted as percent time.

Location	Aggregated: paper or electronic	Time Period	N	d(N)	Sum	d(Sum)	Mean	d(Mean)
	paper	PRE	510	-297	11.837	-7.821	0.02321	-0.004357
NORCAM		post	213	-231	4.016	-7.021	0.01885	-0.004337
INOINOAIVI	ELECTRONIC	PRE	149	751	3.534	11.379	0.02372	-0.007146
		post	900	751	14.912	11.379	0.01657	-0.007 140
	paper	PRE	540	-237	13.244	-10.248	0.02453	-0.014639
Portogo		post	303	-231	2.996	-10.240	0.00989	-0.014039
Portage	ELECTRONIC	PRE	336	737	7.324	7.920	0.02180	-0.007590
		post	1073	131	15.244	1.920	0.01421	-0.007590

Table 2. Paper vs. Electronic Usage

Note: the d() nomenclature denotes change-in that quantity, (POST – PRE)

d(N) = change in the number of observed activities

d(Sum) = change in the sum of percent time of the activities contained in

the grouping indicated

d(Mean) = change in the average percent time elapsed per observed activity

A significant change (POST – PRE) exists for both NORCAM and Portage for activities aggregated into categories of paper and electronic. Also of note are the magnitude and direction of change demonstrated by d(N) and d(Sum):

Change-in, (variable description)	variable	Paper, (aggregated)		ELECTRONIC, (aggregated)			
		NORCAM	Portage	NORCAM	Portage		
Activity count	d(N)	58% reduction	44% reduction	5 fold increase	2 fold increase		
Percent time Sum	d(Sum)	8% reduction	10% reduction	11% increase	8% increase		

Table 3. Paper vs. Electronic Usage

Time and Motion Conclusion

A significant negative change (post – pre) on the variable, percent time, was found for various processes at Portage and NORCAM. The results for NORCAM suggest that productivity (on a time basis) improved for medication orders and renewals, receiving lab/test results, medical records management, phone calls with patients, scheduling patient appointments and revenue cycle. The results for Portage suggest that productivity (on a time basis) improved for medication orders and renewals, writing orders and scheduling tests, receiving lab/test results, medical records management, phone calls with patients, scheduling patient appointments and revenue cycle. Investigators conclude that the implementation of an electronic health record directly improved medication orders and renewals, receiving lab/test results, and medical records management; the electronic health record did not improve productivity associated with clinical notes, transcription and dictation. Furukawa¹ found that electronic medical records have a mixed association with efficiency and productivity during office visits.

In reference to Table 5, N is defined as the aggregate number of distinct activities performed during the Time & Motion observations. The unit for the "Sum" column is hours. The negative d(Mean) can be interpreted as a decrease in the average of percent time required for an activity, which implies increased productivity.

Process	ID Number
Medication Orders/Renewals	1
Write Dx Orders/Scheduling Tests & Referrals	2
Receiving Lab/Test Results	3
Medical Records Management	4
Clinical Notes/Transcription/Dictation	5
Phone - Patient	6
Scheduling Patients in Office	7
Talking - Colleague/Walking Inside	8
Revenue Cycle	9
Remaining Activities Not Under Analysis	0

Table 4. Process Description

Location	MIDHT	Time	N	d(N)	Sum	d(Sum)	Mean	d(Mean)
Location	Process	Period		u(i v)				u(ivicaii)
	0	PRE	426	441	16.914	しし / ちし	0.03970	-0.01933
	4	post	867		17.664		0.02037	
	1	PRE	36	34	1.011	0.161	0.02807	-0.01133
		post	70		1.172		0.01674	
	2	PRE	38	35	1.007	0.695	0.02651	-0.00319
N	3	post PRE	73 34		1.703 0.749		0.02332 0.02203	
	3	post	16	-18	0.749	-11 784	0.02203	-0.01174
0	4	PRE	201		5.522		0.01029	
R		post	521	320	8.336	/ X 14	0.02747	-0.01147
	5	PRE	254		5.746		0.02262	
С		post	99	-155	2.306	-3 4411	0.02330	0.00067
A	6	PRE	81		2.373		0.02930	0.00===
	-	post	110	29	2.368	-0.005	0.02153	-0.00777
M	7	PRE	67	1/7	1.398		0.02086	0.00657
		post	214	147	3.057	1.659	0.01428	-0.00657
	8	PRE	232	-20	3.054	-0.140	0.01316	0.00058
		post	212	-20	2.914	-0. 1 4 0	0.01375	0.00030
	9	PRE	60	28	1.240	0.237	0.02067	-0.00388
L		post	88		1.477		0.01679	0.00000
	0	PRE	770	687	29.032	/ 11/.5	0.03770	-0.01639
		post	1457		31.056		0.02131	
	1	PRE	74	-48	2.358	-/111116	0.03186	-0.01833
		post	26		0.352		0.01353	
P	2	PRE	104	5	2.356	_11 h /4 1	0.02266	-0.00681
	3	post	109		1.728		0.01585	
0	3	PRE	42 40	-2	0.900 0.691	-0.209	0.02143 0.01726	-0.00417
r	4	post PRE	313		9.066		0.01726	
	7	post	484	171	5.529	5.5.5/	0.02090	-0.01754
t	5	PRE	240		5.419		0.02258	
а		post	270	30	5.847	0.428	0.02166	-0.00092
a	6	PRE	137	100	5.154	0.470	0.03762	0.00550
g	-	post	246	109	2.981	-/ 1/.3	0.01212	-0.02550
e	7	PRE	32	224	0.702		0.02194	0.04406
_		post	263	231	2.810	/ 100	0.01068	-0.01126
	8	PRE	351	201	5.376	1.035	0.01532	-0.00370
		post	552	201	6.411	1.033	0.01161	-0.00370
	9	PRE	9	97	0.623	しいとコンコ	0.06917	-0.05563
		post	106	31	1.435	0.012	0.01353	-0.00000

Table 5. Time & Motion Summary

Survey opportunities were made available to providers so that qualitative assessment of user satisfaction of the Allscripts EHR could be undertaken. The survey used was retrieved from the Agency for Healthcare Research and Quality (AHRQ) survey compendium and was modified for project use. An attempt was made to determine if satisfaction changed over time (June 2010,

November 2010 and May 2011) but a low sample size prevented analysis. Below are descriptive results of some important questions (n=26):

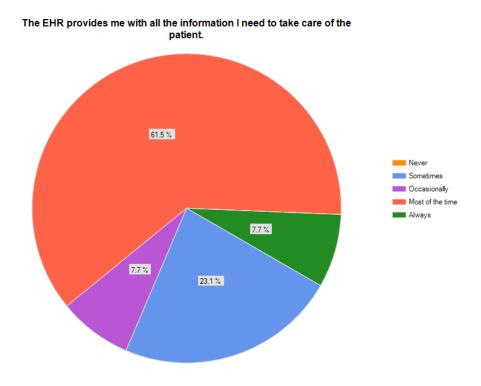


Figure 1. EHR Utility.

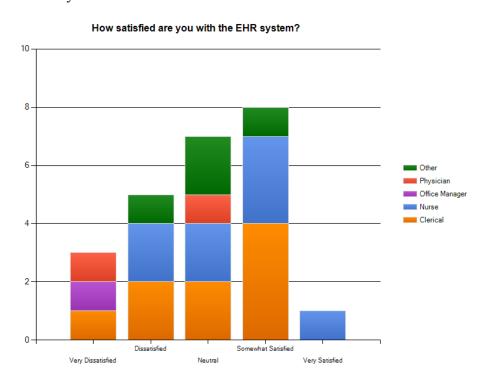


Figure 2. Satisfaction with EHR.

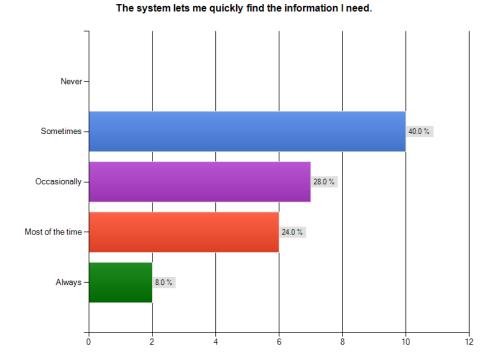


Figure 3: EHR Satisfaction Results

Survey Conclusion

Overall, the staff at Portage and NORCAM indicated an ambivalence regarding satisfaction of the EHR implementation with almost one third stating a neutral satisfaction. When looking at position type, no apparent trends were noted (Note: "Other" most likely includes some physicians). These satisfaction results are much lower than those reported by DesRoches et al regarding a 2008 national survey of physicians on EHRs. Only 34% of CMMC staff was satisfied whereas 90% of physicians surveyed nationally were satisfied. Despite the finding of neutral satisfaction, descriptive analysis of certain questions indicates a positive perception of the EHR. Aggregating the answer choices for question twenty (q0020) as either difficult or easy shows that a majority of respondents indicated the following activities were easier when using the EHR as compared to previous routines:

- Documenting allergies
- Documenting CPT and ICD-9 codes for billing purposes
- Keeping problem lists updated
- Reviewing laboratory and radiology results
- Writing and renewing prescriptions
- Monitoring medication safety during prescribing
- Communicating referral information to specialists

Furthermore, approximately 50% of respondents agreed that the EHR enabled them to accomplish tasks more quickly, enhanced job effectiveness and made it easier to do their job. Whereas 45% of respondents state they work longer hours to see the same number of patients. Also, no consensus that the EHR caused disruptions to their workflow was found.

Written comments most often cited suggest that staff appreciated not having to pull and refile paper charts, access to hospital information (e.g. lab/rad results) was much easier (direct interface to Allscripts), and the benefits of ePrescribing. On the negative side, staff members were frustrated with the multiple screens and not being able to quickly locate information, creating clinical notes was too cumbersome, determining which tests were ordered was more difficult and more training was needed.

Although the significance of the following statistical analysis cannot be interpreted as definitive due to violations resulting from the sample size, the results do generally support the conclusions drawn from the descriptive analysis above.

Statistical Analysis of EHR Survey Results (n=26):

Crosstabs were performed over questions 1-19 (rows) on questions 22, 27, 28, 29, 30 and 31 (columns). Chi-square was used to test for significance between the columns over the rows. Unfortunately, the sample size produced untenable cell counts and significance testing could not be performed. Furthermore, a crosstab of question 30 and 31 did not produce a significant result using Chi-square; nor did question 22 with 30. Analyzed independently, questions 20 and 21 yielded slightly positive responses, overall. The low sample size overall and decline in responses over time prevented a longitudinal analysis of survey data as designed. Please refer to Appendix 1 for a copy of the survey results.

	S04_3_q0022	S04_8_q0027	S04_9_q0028	S04_10_q0029	S04_11_q0030	S04_12_q0031
S02_q0001	0.274	0.108	0.295	0.008	0.200	0.085
S02_q0002	0.063	0.568	0.615	0.032	0.511	0.005
S02_q0003	0.020	0.644	0.390	0.188	0.267	0.037
S02_q0004	0.018	0.433	0.356	0.728	0.080	0.102
S02_q0005	0.011	0.719	0.347	0.739	0.817	0.012
S02_q0006	0.225 (0.378)	0.431 (0.695)	0.018	0.743	0.027 (0.073)	0.053
S02_q0007	0.255	0.988	0.398	0.379	0.203	0.013
S02_q0008	0.320	0.486	0.378	0.389	0.037	0.094
S02_q0009	0.819	0.793	0.727	0.384	0.039	0.322
S02_q0010	0.206	0.930	0.059	0.837	0.022	0.049
S02_q0011	0.161	0.550	0.223	0.753	0.759	0.567
S02_q0012	0.151	0.253	0.210	0.012	0.648	0.330
S03_1_q0013	0.030	0.136	0.511	0.185	0.626	0.169
S03_2_q0014	0.070	0.574	0.338	0.255	0.763	0.592
S03_3_q0015	0.362	0.113	0.957	0.424	0.917	0.920
S03_4_q0016	0.332	0.756	0.966	0.238	0.799	0.691
S03_5_q0017	0.041	0.105	0.556	0.018	0.317	0.093
S03_6_q0018	0.023	0.134	0.022	0.255	0.378	0.160
S03_7_q0019	0.229	0.596	0.055	0.753	0.039	0.133

NOTES:

- 1) Values in this table represent the Pearson Chi-square result except where indicated below.
- 2) () indicate the asymptotic significance as calculated by the Fisher's Exact Test for a 2x2 matrix
- 3) italics indicate that fewer than 25% of the cells have an expected count < 5
- 4) All results (except those in italics) result from a matrix that has at least 33% of the cells with an expected count < 5. As such, these results should not be used to make concrete inferences as to significance.

Table 6. Chi-Square p-values for Crosstabs of Survey Questions

Crosstab								
			S04_3_ No	Total				
	No S04_11	Count	5 _a	13 _a	18			
_		% within S04_3_q0022	71.4%	72.2%	72.0%			
_q0030		Count	2 _a	5 _a	7			
	Yes	% within S04_3_q0022	28.6%	27.8%	28.0%			
		Count	7	18	25			
Tota	al	% within S04_3_q0022	100.0%	100.0%	100.0%			

Each subscript letter denotes a subset of S04_3_q0022 categories whose column proportions do not differ significantly from each other at the .05 level.

Chi-Square Tests					
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi- Square	.002ª	1	.968		
Continuity Correction ^b	.000	1	1.000		
Fisher's Exact Test				1.000	.663
N of Valid Cases	25				

a. 1 cell (25.0%) has an expected count less than 5. The minimum expected count is 1.96.

b. Computed only for a 2x2 table

Table 7. Crosstab Results and Chi-Square p-value for Survey Questions 11 and 22

		Crosstab				
			S04_3	_q0022	Total	
			No	Yes	Total	
	-	Count	4 _a	2 _b	6	
	DISsatisfied	% within S04_3_q0022	57.1%	11.1%	24.0%	
	VERY	Count	1 _a	2 _a	3	
	DISsatisfied	% within S04_3_q0022	14.3%	11.1%	12.0%	
S04 12	neutral	Count	2 _a	5 _a	7	
_q0031		% within S04_3_q0022	28.6%	27.8%	28.0%	
	somewhat satisfied	Count	0 _a	8 _b	8	
		% within S04_3_q0022	.0%	44.4%	32.0%	
	VERY	Count	0 _a	1 _a	1	
	satisfied	% within S04_3_q0022	.0%	5.6%	4.0%	
		Count	7	18	25	
	Total	% within S04_3_q0022	100.0%	100.0%	100.09	

Each subscript letter denotes a subset of S04_3_q0022 categories whose column proportions do not differ significantly from each other at the .05 level.

Chi-Square Tests								
	Value	df	Asymp. Sig. (2-sided)					
Pearson Chi- Square	7.993ª	4	.092					
N of Valid Cases	25							

a. 8 cells (80.0%) have expected count less than 5. The minimum expected count is .28.

Table 8. Crosstab Results and Chi-Square p-value for Survey Questions 12 and 22

S04_11_q0030 * S04_12_q0031 Crosstabulation

			S04_12_q0031					
			DISsatisfied	VERY DISsatisfied	neutral	somewhat satisfied	VERY satisfied	Total
S04_11_q0030	No	Count	2 _a	2 _a	7 _a	7 _a	1 _a	19
		% within S04_12_q0031	33.3%	66.7%	87.5%	87.5%	100.0%	73.1%
	Yes	Count	4 _a	1 _a	1 _a	1 _a	0 _a	7
		% within S04_12_q0031	66.7%	33.3%	12.5%	12.5%	.0%	26.9%
Total		Count	6	3	8	8	1	26
		% within S04_12_q0031	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Each subscript letter denotes a subset of S04_12_q0031 categories whose column proportions do not differ significantly from each other at the .05 level.

Chi-Square Tests							
			Asymp. Sig. (2-sided)				
	Value	df	(2-sided)				
Pearson Chi-Square	6.940 ^a	4	.139				
N of Valid Cases	26						

a. 8 cells (80.0%) have expected count less than 5. The minimum expected count is .27.

Table 9. Crosstab Results and Chi-Square p-value for Survey Questions 30 and 31

Statistical Analysis of Productivity Data (n = 6 providers (control), 5 providers (EHR)):

Initial statistical analysis obviated the necessity for additional data points to achieve sufficient symmetry and homogeneity to produce an analyzable dataset. A protocol modification was necessary to further clarify the time period to be used (January 2007 – February 2010) for analysis, which was approved by Conemaugh IRB on December 9, 2011.

Quarterly data was obtained for years 2007 through 2011. Both a MANOVA and RM-(m)ANOVA were attempted; however, underlying assumptions for those tests were violated. The data was reorganized and recast to conform to a paired-t and a standard independent t-test. Since Year 2007 only contained data for the following variables, Charges, Units, Encounters, and Office Hours Worked, it could not be included in the paired-t or independent t-test derived from the paired-t setup. Furthermore, the calendar quarters for all years were not consistent due to the implementation. To minimize the impact of potential periodicity, the data pairing for the paired-t used 2009, 2010, and 2011 data. The paired-t test was used to investigate the within-group change between the post and pre time periods. Due to the testing of multiple dependent variables, the test-wise alpha was adjusted so that the overall alpha remained 0.05. The following calculated variables were produced so as to provide for a more direct comparison between the control and intervention groups: Charge/Unit, Encounters/Hr, and Total RVUs per Encounters/Hour. The difference (post-pre) was calculated and a standard t-test was applied to test if the mean difference was statistically significant between groups. No statistical significance was found.

Despite the finding of no statistical significance between the control and intervention group, the change (post - pre) in the mean difference of encounters per hour improved for the intervention group and not the control group (0.28 vs -0.086). A similar improvement was also noted for Total RVUs (546 vs 316). In other words, EHR users likely realized an increase in patients per hour and productivity when compared to the paper-based physician offices.

Study Closure:

Subject study was closed with Conemaugh IRB on April 2, 2012. Final report and supporting documents were delivered to USAMRMC ORP HRPO and found to be acceptable on April 19, 2012 (refer to Appendix 2).

Subtask 1.2 Enhance the service-based HIE infrastructure and services to support further exchange of digital medical imaging information in a rural setting.

Extending the McKesson PACs, Radiology Information System (RIS) and Dolbey Digital Dictation system used at Memorial Medical Center to Miners and Meyersdale Medical Centers allowed Conemaugh to achieve consistency across the health system when it comes to radiology imaging, report management, and access. This was of great value to the physicians and patients of the health system allowing a reduction in the redundancy of diagnostic testing and ultimately provides better care to our patients.

Memorial Medical Center's MIS Department worked closely with resources from McKesson's MRM and HMI divisions. Relevant system design and table builds were identified. Workflow processes among the three entities were reviewed and altered to accommodate the new integrated process. Workflow and policies for establishing Miners and Meyersdale on the Memorial PACS system were designed. Radiologists and technologists reading and workstations were purchased, configured, and installed at both facilities, and the set up of off-hour image transmission was completed. In addition, Vidar film digitizers, computerized radiology (CR) devices, document scanners, and Dolbey dictation equipment and software licenses were obtained and installed at both facilities. McKesson PACS software licenses for MyMC and MiMC facilities were purchased, and staff from Miners and Meyersdale were trained by Memorial Radiology and Management Information Systems Departments on the use of PACS. Workgroups were built into PACS to accommodate the workflow for Miners and Meyersdale and the networking group provided needed cabling and networking services to provide workstation and modality network connectivity and access from both locations.

On July 1, 2009, PACS went live at Miners and Meyersdale for image transfer only. Radiology staff at both locations continued to be trained on RIS functionality. Tables were identified to be scripted for the test environment and cross-reference exam master, charge master was added to the spread sheet to be used for scripting in large tables. McKesson upgraded the test server and retested the application. Reports that were added by Miners and Meyersdale were tested, but were found to have an incorrect footer. Application testing/HRM HIM integration testing occurred, with status changes from HMI to HRM not working. This was later corrected. The

following HRM tables were made available in Live: Facilities, Locations, Modalities, Work list, Film Libraries, Film jacket types, and locations and Pt Class. The following tables were edited in Live to be Enterprise wide: Admin Route, Pt Condition, and Normals. EMPI/ADT/Integration testing was completed.

Productive use via the McKesson Care Portal was implemented on January 19, 2010 and post-live support was provided to Miners and Meyersdale. Weekly calls continued between Miners, Meyersdale, and CMMC to identify post-live issues. McKesson assisted with vendor identified issues. Calls continued weekly to validate processes and resolve issues. McKesson continued to be engaged to assist with patient merge issues.

Subtask 1.3 Research and evaluate the ability to electronically exchange digital images and how this functionality will affect the delivery of patient care within a rural health care system, to include an analysis on provider productivity, throughput, duplicative testing and continuity of care.

Study 16192.1

The Initiate Enterprise Master Patient Index (EMPI) software was used to correlate and match different medical record numbers across facilities for the same patient. Due to this procedure, duplicate tests within the same facility were identified by the study team with a high degree of confidence. Significance testing for hypothesis #1 was completed with the following results for the count of tests originating at Miners/Meyersdale and duplicated at Memorial (CPT 71010, 71020, 70450) by time period is presented below:

PRE	(haseline)	POST			
(baseline)		Phase 1	Phase 2		
2008	200	2010			
July through December	January through June	July through December	I January through June		

Table 10: Study Time Period

A Chi-Square test of independence applied to either Days between date of service (DOS) or aggregated Days between DOS over time period did not yield a significant result yet a 7% reduction in duplicate imaging is noted. No statistical significance was found by CPT code. Radiology volume data by CPT code for Miners and Meyersdale was homogeneous between the pre and post data sets. The results were more favorable than what You² discovered in a similar duplicate imaging study in Canada. You found a 0.1% reduction in chest x-rays and 0.2% reduction in CT scans of the head whereas CMMC researchers found a 2.9% reduction in chest x-rays and a 26.8% reduction in CT scans of the head for the study time period.

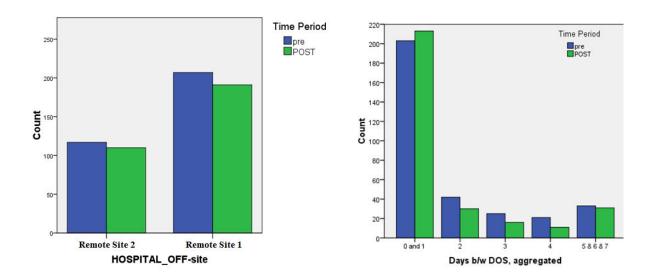


Figure 4. Duplicate Tests by Hospital and Days Between Date of Service.

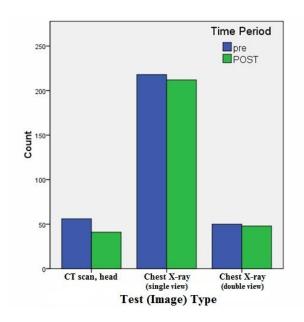


Figure 5. Duplicate Tests by Image Type.

Aggregated Days b/w DOS	CPT Code All – study	pre	POST	Total	Change, (POST - PRE)
0 & 1	specific	203	213	416	10
2		42	30	72	-12
3		25	16	41	-9
4		21	11	32	-10
5 & 6 & 7		33	31	64	-2
Column Totals:		324	301	625	-7%

Table 11. Raw Data Counts.

PACS User Reports

A randomized proportionate sample of PACS users on the CMMC medical staff were identified to collect data on their viewing of images that originated from Miners and/or Meyersdale facilities during October – December 2009 and April – June 2010. Management Information Systems provided reports to the study team, 38% (27/70) of physicians had applicable data. When comparing POST Phase 1 & 2 data, count is very similar so they were consolidated.

As depicted below, the most active users of the PACS system in terms of viewing images originating from Miners and Meyersdale are Emergency Medicine and Trauma physicians. This result is expected as Conemaugh Memorial Medical Center (CMMC) is a tertiary care hospital with a Level I trauma center. The next level includes Otolaryngology, Urology, and Pulmonary. A third level includes General Surgery, Orthopedics and Neurosurgery.

Specialty	Studies From Remote Sites Viewed via PACS
Emergency Medicine	65
Trauma	51
Otolaryngology	35
Urology	34
Pulmonology	31
General Surgery	28
Orthopedics	27
Neurosurgery	26
Internal Medicine	18
Vascular	10
OB/GYN	5
Nephrology	2

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Table 12. PACS Usage by Specialty.

Physician Surveys

The qualitative surveys collected that indicated that the physician never used PACS to access images from Miners and Meyersdale were removed from the dataset before analysis. The remaining responses (n=55) formed the dataset of analysis. Although not statistically significant (alpha=0.05), the bar chart below clearly shows that those respondents who indicated having previous experience with PACS used the system more than those who had not had previous PACS experience.

Investigators decided to focus on the following questions:

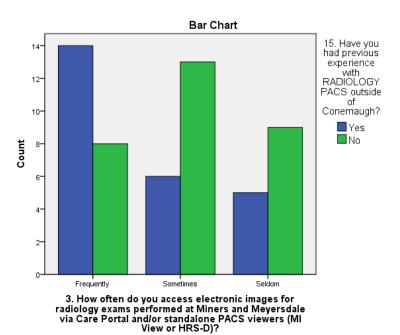


Table 13. Chi-Square Tests							
	Value	df	Asymp. Sig. (2-sided)				
Pearson Chi- Square	4.944ª	2	0.084				
Likelihood Ratio	5.002	2	.082				
Linear-by-Linear Association	3.270	1	.071				
N of Valid Cases	55						

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 6.36.

Figure 6: Frequency of PACS Usage.

The results suggest that the PACS implementation at rural hospitals (Miners and Meyersdale) had a positive impact on providers and patients. A majority of physicians (87%) believed that image access has improved productivity whereas 81% of physicians believed that immediate PACS image access has improved physicians' ability to make decisions regarding patient care. Furthermore, 70% of physicians agree that immediate PACS image access has reduced the number of exams reordered because images taken previously were not known about or not available in a timely manner.

Productivity:7a. My productivity has improved because of image access. (Please check ONLY one response)

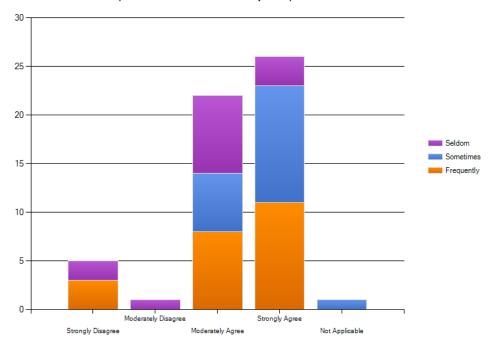


Figure 7. Productivity Improvement.

Decision Making:8a. Immediate PACS image access has improved my ability to make decisions regarding patient care. (Please check ONLY one response)

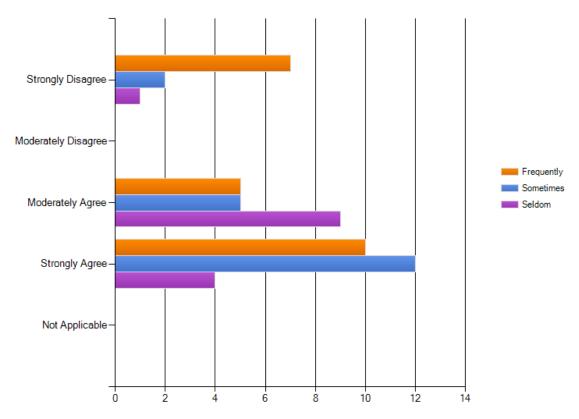


Figure 8. Improved Decision-Making.

Effect on Reordering of Exams:10a. Immediate PACS image access to films performed at Miners/Meyersdale has reduced the number of exams reordered because the images previously were not available (lost or located elsewhere) when I needed them. (Please check ONLY one response)

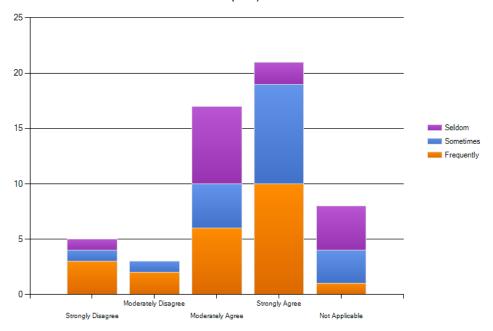


Figure 9. Reduction of Duplicate Exams.

Questions 6-10 were analyzed using the original scale, a 5 level Likert scale, and an aggregation (collapsing) of that scale comprised of 3 levels:

Answer Choice on survey:	Strongly	Disagree	Agree	Strongly	Not
Answer Choice on survey.	Disagree			Agree	Applicable
Answer code for survey question:	1	2	3	4	0
Answer code for Aggregation:	1			0	

Table 14. Likert Scale Aggregation.

Those questions related to Productivity (6a, 6b, 7a, 9a, 10a) individually and collectively indicated an overall positive (Agree) response as demonstrated by both the bar (column) graphs and means. Likewise, the questions (6c, 8a) related to decision making also indicated an overall positive (Agree) response, both individually and collectively.

Question		min	MAX	N	/lean
6. a) RADIOLOGY PACS has reduced the time I must wait to review an image.	55	1	4	3.45	
6. a) aggregated: Disagree, Agree, N/A	55	1	2	1.87	
6. b) I access images more frequently with RADIOLOGY PACS than I did with film.	54	0	4	3.35	
6. b) aggregated: Disagree, Agree, N/A	54	0	2	1.76	
RADIOLOGY PACS has facilitated consultation between myself, other clinicians and/or radiologists at other healthcare locations.	55	0	4	3.05	
6. c) aggregated: Disagree, Agree, N/A	55	0	2	1.69	
7a. My productivity has improved because of image access. (Please check ONLY one response)	55	0	4	3.22	
7. a) aggregated: Disagree, Agree, N/A	55	0	2	1.85	
Decision Making: 8a. Immediate PACS image access has improved my ability to make decisions regarding patient care. (Please check ONLY one response)	55	1	4	3.11	
8. a) aggregated: Disagree, Agree, N/A	55	1	2	1.82	
Effect on Patient Transfers: 9a. Immediate PACS image access has reduced the number of patient transfers between facilities due to the ability to share images and consult remotely. (Please check one response)	55	0	4	1.73	
9. a) aggregated: Disagree, Agree, N/A	55	0	2	1.00	
Effect on Reordering of Exams: 10a. Immediate PACS image access to films performed at Miners/Meyersdale has reduced the number of exams reordered because the images previously were not available (lost or located elsewhere) when I needed them.	54	0	4	2.70	
10. a) aggregated: Disagree, Agree, N/A	54	0	2	1.56	

Table 15. Descriptive Statistics.

Hypothesis testing of those questions indicate that the response per category most probably represented a real difference in respondent opinion. With the exception of question 9, the results of the hypothesis testing did not change for the aggregations of the responses of those questions. Question 9 yields the opposite result upon aggregation due to the relatively high number of "Not Applicable" responses. [Asymptotic significance at the 0.05 level is shown for all hypothesis testing.]

Null Hypothesis	Test	Sig.	Decision				
The categories of 6. a) RADIOLOGY PACS has reduced the time I must wait to review an image. occur with equal probabilities.	One-Sample Chi-Square Test	.000	Reject the null hypothesis.				
The categories of 6. b) I access images more frequently with RADIOLOGY PACS than I did with film. occur with equal probabilities.	One-Sample Chi-Square Test	.000	Reject the null hypothesis.				
The categories of 6. c) RADIOLOGY PACS has facilitated consultation between myself, other clinicians and/or radiologists at other healthcare locations. occur with equal probabilities.	One-Sample Chi-Square Test	.000	Reject the null hypothesis.				
The categories of Productivity: 7a. My productivity has improved because of image access. (Please check ONLY one response) occur with equal probabilities.	One-Sample Chi-Square Test	.000	Reject the null hypothesis.				
The categories of Decision Making: 8a. Immediate PACS image access has improved my ability to make decisions regarding patient care. (Please check ONLY one response) occur with equal probabilities.	One-Sample Chi-Square Test	.030	Reject the null hypothesis.				
The categories of Effect on Patient Transfers:							
9a. Immedicate PACS image access has reduced the number of patient transfers between facilities due to the ability to share images and consult remotely.	One-Sample Chi-Square Test	.010	Reject the null hypothesis.	The categories of 9. a) aggregated: Disagree, Agree, N/A occur with equal probabilities.	One-Sample Chi-Square Test	.748	Retain the null hypothesis
(Please check one response) occur with equal probabilities.							
The categories of Effect on Reordering of Exams: 10a. Immediate PACS image access to films performed at Miners/Meyersdale has reduced the number of exams reordered because the images previously were not available (lost or located elsewhere) when I needed them. (Please che occur with equal probabilities.	One-Sample Chi-Square Test	.000	Reject the null hypothesis.				

Table 16: Hypothesis Testing

Additionally, physicians overwhelmingly indicated that viewing images using PACS rather than on disk (report included) is more beneficial.

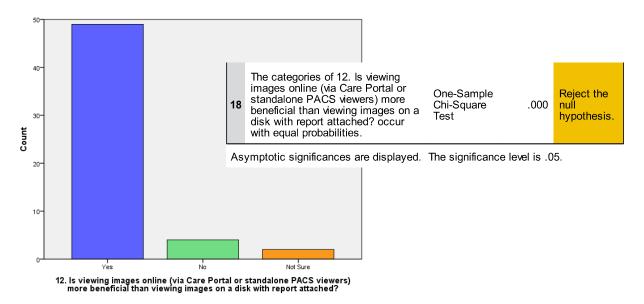


Figure 10. Viewing Images – Electronic vs. CD.

Study Conclusion:

In summary, the analysis strongly indicates that, overall, CMMC physicians believed that the implementation and availability of PACS at the rural facilties is beneficial relative to productivity, decision making, and duplicate testing. Although the results were not statistically significant, a 7% reduction in duplicated chest x-rays and CT scans of the head (0-7 days) is noteworthy and does mildly align with positive physician opinion. Finally, the implementation of PACS technology clearly has reduced costs and patient exposure to radiation.

Study Closure:

This study has been completed and closed with Conemaugh IRB on July 14, 2011. Final report and supporting documents were delivered to USAMRMC ORP HRPO and found to be acceptable on August 29, 2011 (refer to Appendix 3).

Manuscript:

A study manuscript was completed and submitted to Radiology on April 12, 2012. Unfortunately, CMMC received notification on May 10, 2012 that it was not accepted for publication. Reviewer comments have been discussed by the study team and minor edits were completed before submission to Telemedicine and eHealth in July 2012. The manuscript was not accepted for publication in Telemedicine and eHealth. The study team is again reviewing

reviewer comments and is in the process of selecting another journal for submission for publication. Please refer to Appendix 4 for a copy of the manuscript.

Subtask 1.4 Deploy (via portal technology) a pilot demonstration of the electronic exchange of private sector ambulatory medical records with the DoD and other selected stakeholders using test data.

The second phase of MIDHT further refined the CHS Portal capabilities created during Phase One to better align with the Military Health System (MHS) strategic goals and the Nationwide Health Information Network (NwHIN). MIDHT continued to identify lessons learned/best practices that benefited the MHS environment, stakeholders in Southwestern PA and private sector hospitals/health systems nationwide.

Authorization to Proceed was executed with subcontractor Northrop Grumman (NG) on June 10, 2009. A complete Technical Services Agreement was executed on July 24, 2009 after SOW review by LCDR Steve Steffensen.

Project representatives attended the NwHIN CONNECT conference on June 29-30, 2009 and held a meeting with TATRC leadership to discuss future work. Project representatives viewed the NwHIN CONNECT Release 2.1 webinar on July 28, 2009. The webinar reviewed changes made to CONNECT code in v2.1, as well as reviewing the CONNECT architecture. NG team members initiated meetings with the TATRC Advanced Concepts Team (ACT) and ONC leadership to discuss the Virtual Lifetime Electronic Record (VLER) – San Diego development work and the feasibility of using the Patient Ancillary Web Services (PAWS) to extract data from AHLTA. Northrop Grumman representatives, Steven Clark and Allen Barger, attended the CONNECT "Code-A-Thon" event on August 27, 2009. The event, which was attended by various corporations and federal organizations, presented interested HIT professionals with an opportunity to collaborate with the CONNECT development team. While at the event, NG representatives participated in:

- o Downloading, installing, and compiling the CONNECT source code
- O Discussions around the SoapUI web service testing software and participation in demonstrations on how to write tests, create messages, and perform specific actions in both the free and professional versions of the product
- Discussions around the need to have a test NHIN platform and the benefits that would be realized by having such a platform to test CONNECT configurations against
- o Discussions around "best practices" for CONNECT development

NG configured development and test environments in Johnstown, Salt Lake City and Chantilly, including standing up a DoD and CHS gateway with CONNECT v. 2.1.5 code (open-source). NG designed VLER spreadsheet for mappings of data types and constructed mappings of the PAWS Connector for each of the four data types:

Allergies: PAWS to CAL, CAL to C83
 Problems: PAWS to CAL, CAL to C83
 Patient Info: PAWS to CAL, CAL to C83
 Medications: PAWS to CAL, CAL to C83

On November 16, 2009, NG delivered a fully functional code drop to the Federal Healthcare Architecture (FHA) team, thus meeting SOW Deliverable 16. This drop was made via *Dropbox*, a repository used by the TATRC/NG/FHA developers. In addition to delivery of binary code, Northrop Grumman also provided Phase 1a source code to FHA, with the intent of the FHA team folding it into the CONNECT v2.1.5 baseline for release with CONNECT v2.3. Northrop Grumman provided a "Software Design Document" and "System Installation Guide" to the Defense Health Information Management System (DHIMS) and FHA representatives, among other documents. NG provided considerable talent and resources to the Department of Defense, which allowed them to successfully meet VLER timelines and objectives.

The ability to connect to the CHS Initiate and Allscripts servers (within Conemaugh's data center) was verified by Northrop Grumman. Conemaugh continued to integrate and deliver urgent fixes for any bugs found during the FHA install and testing process for VLER 1a. Northrop Grumman adapted their clinical viewer for MIDHT use and integrated application with the Universal Inbox for correct displaying of C32's.

John Hargreaves, Thomas Simunich and Allen Barger represented MIDHT at the HIMSS conference and exhibition during the first week of March 2010 in Atlanta, GA. This provided a good opportunity for collaboration with military and government representatives. Our successful demonstration showed a bi-directional health information exchange of test C32 documents (refer to Appendix 5 for sample screenshots) between Conemaugh and DoD utilizing the NwHIN CONNECT v2.1.5 architecture.

Fields to display prefix, suffix, middle initial and gender were added to the Clinical Viewer GUI. Development to enable pulling this information back from the adapter was completed. Development was completed to allow the Universal Inbox to accept an encrypted patient ID. Work was completed that allowed Universal Inbox to be "publicly" viewed (outside of the internal NG 10-net). Work was completed to remove any PHI from displaying within the Clinical Viewer URL. NG delivered all VLER 1a source code to a DHIMS representative on March 12 and March 17, 2010.

Allen Barger attended the CONNECT Code-a-Thon conference in Miami, FL from April 27-29, 2010, where he:

- Worked with the TATRC Advanced Concepts Team (ACT) on a fix for the document return latency issue
- Spoke to participants about the private sector implementation of the document assembler at a class taught by members of the TATRC ACT team

CONNECT v2.4.1 was subsequently installed on the local Johnstown development environment and the local environment in Salt Lake City, Utah.

Subtask 1.5 Perform a technical feasibility study to focus on repurposing the BHIE-AHLTA web services toward the existing NHIN Federal Adapter for the purpose of standards based exchange of Military Health System data domains with private sector partners.

Deliverable was completed on September 30, 2009. The document was emailed to LCDR Steve Steffensen on October 2, 2009.

Subtask 1.6 Begin development on a private sector version of the Federal Gateway/Adapter (work to be based on the code that is anticipated to be available from ONC) using interoperable HITSP standards to progress the goals of this national effort.

Despite persistent prodding, the Conemaugh MIS team ultimately concluded that Allscripts was not willing to assist in any way on the development of webservices for a query-based response of a Continuity of Care Document (CCD) as initially planned. An XML-based CCD was currently available only as a manual "push." After consultation with Northrop Grumman, the MIS team decided to utilize the CONNECT "Document Assembler" approach utilizing HL7 messaging to build a CCD from individual data domains from Allscripts (patient demographics, allergies, medications and problems).

Conemaugh implemented a partial Common Access Layer Service interface to return to a remote partner HL7 v3 clinical document architecture (CDA) documents from an underlying clinical information system. The Common Access Layer Service Interface web service was developed in Microsoft.NET. AllScripts TouchWorks was the underlying clinical information system from which data was provided. No application programming interface existed within the clinical information system by which to return information. Therefore, a web service was implemented to retrieve data directly from the clinical system's backend database via a mix of pre-existent stored procedures and custom database queries. Data domains included active patient demographics, problems, allergies and medications. Additionally, 13 Conemaugh test patients were created to match the selected TATRC CDR patients. Data was entered into the Allscripts EHR for testing purposes. TATRC arranged AHLTA VM (test) access for our HIMSS demo with FHA for displaying of Conemaugh data within AHLTA.

In addition, the Allscripts Adapter was created:

- NG development team worked in conjunction with CHS personnel to stand-up CHS Allscripts Adapter
- o NG development team provided CHS personnel with appropriate WSDL's
- o NG development team created connection to existing CHS Allscripts Adapter
- o Achieved a successful return of care records from the CHS Allscripts system

Conemaugh project members reviewed and added specific Allscripts (version 11.1.7.283) documentation to the "CHS Adapter Installation and Configuration Guide" created by Northrop Grumman. In addition, all related source/binary code was compiled and burned onto cd's for distribution to TATRC on April 7, 2010 (in addition to NG code).

Conemaugh representatives held an introductory phone call on April 13, 2010 with the Department of Veterans Affairs (Tim Cromwell) to discuss the possibility of a production health information exchange pilot in SW Pennsylvania. Conemaugh finalized its review/completion of the *NHIN Application for New Participants* (including DURSA). Conemaugh was informed of the NHIN On-boarding process and required conformance testing.

Subtask 1.7 Perform an assessment of the volume of cases that Conemaugh physicians have with SSA regarding veteran/military disability claims and assess provider satisfaction with existing SSA process for information gathering and submission.

The provider survey, assessing the submission process of medical information for Social Security disability cases, was distributed to various office managers within the Conemaugh Health System in June 2010. Fifty one (n=51) providers responded to the survey as depicted below.

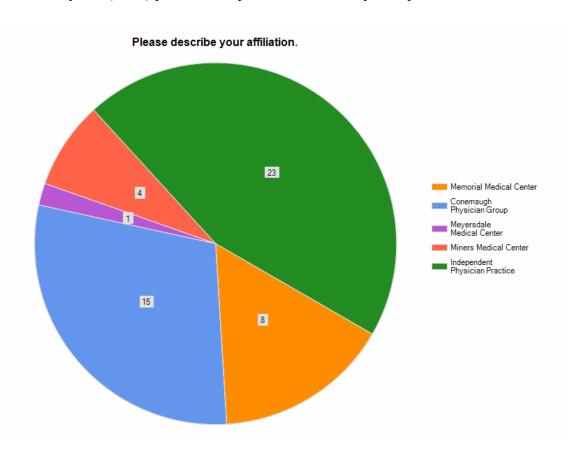


Figure 11. Survey Respondents by Affiliation.

Investigators selected the following questions as the most important to understand the current landscape and assess future provider acceptance of an electronic record submission process (e.g. Nationwide Health Information Network) to the SSA.

Chi-Square test was used to test for independence between question response choices. Independence was found for the response choices for Q3, Q5, Q6 and Q9. Independence cannot be stated for the answer choices of Q10. The Mann-Whitney test was employed to investigate the difference between the responses grouped into CHS and Independent Physician Practice. No between group significance was found for any question. Additionally, the response set was grouped into CHS, CPG, and Independent Physician Practice. Using the Kruskal Wallis test, no between group significance was found for any question.

In order to increase the count for statistical hypothesis testing, the 5-choice scale contained in the original survey was reduced to a 3-point scale -- unsatisfied (sum of very unsatisfied and unsatisfied), neutral, and satisfied (sum of satisfied and very satisfied) for Q9. Since only 5 responses were unsatisfied, independence (by Chi-square test) was found between that choice and each of the other two. Next, the neutral response count versus that of satisfied was tested. No independence was shown. By the Mann-Whitney test, no significance was found when the response set was grouped into CHS and Independent Physician Practice. Likewise, the Kruskal Wallis test did not show significance when the response set was grouped into CHS, CPG, and Independent Physician Practice. Therefore, the hypothesis that Conemaugh providers would prefer an electronic system for submission of medical records to the SSA rather than the existing paper system was not accepted.

Question	Answer Options	Response Percent	Response Count, (n)
	0-10	76.5%	39
2 0	11-20	15.7%	8
3. On average, how many requests for medical	21-30	5.9%	3
records do you receive monthly regarding SSA disability cases?	31-40	2.0%	1
	41-50	0.0%	0
	51+	0.0%	0
	0-10%	93.9%	46
5. On average, what percent of those patient	11-25%	6.1%	3
requests involve military beneficiaries or	26-50%	0.0%	0
veterans (e.g. TRICARE)?	51-75%	0.0%	0
	76-100%	0.0%	0
	0-15 minutes	28.6%	14
	16-30 minutes	44.9%	22
6. On average, how long does it take to	31-45 minutes	22.4%	11
complete and send the proper paper medical records for one patient?	46-60 minutes	4.1%	2
medical records for one patient?	1-2 hours	0.0%	0
	2 hours +	0.0%	0

Question	Answer Options	Response Percent	Response Count, (n)		
	Very unsatisfied	2.0%	1		
	Unsatisfied	8.2%	4		
	Neutral	49.0%	24		
	Satisfied	36.7%	18		
9. Please rate your level of satisfaction with the	Very Satisfied	4.1%	2		
SSA medical record submission process.	Reduction from 5 choice to 3 choice Likert				
	scale				
	Unsatisfied	10.2%	5		
	Neutral	49.0%	24		
	Satisfied	40.8%	20		

10. Would you personally use an electronic processing system for submitting medical	Yes	34.8%	16
records that would result in significantly reduced SSA determination times for your	No	23.9%	11
patients (e.g. Nationwide Health Information Network)?	Need More Information	41.3%	19

Table 17. SSA Survey Responses.

Arm 2: The Impact of Consumer Informatics in the Chronic Care Model: Metabolic Syndrome and Gestational Diabetes in a Rural Setting (A-15835.1)

- **Subtask 2.1** Deploy HIE tools for patient and community outreach in varied rural environments.
- **Subtask 2.2** Research and evaluate the impact of a personal health record (PHR) on provider(s) and consumer(s) with particular focus on chronic disease prevention.
- **Subtask 2.3** Research and evaluate the impact of web-based secure messaging, online consultations, prescription renewals, and appointment scheduling on consumer awareness and their ability to effectively self manage their health compared to those consumers not using a PHR.

Background

Chronic Disease

The burden of chronic disease in the United States is great and will increase over time. Prevention of these conditions is essential in order to increase the health and quality of life of the aging population while decreasing the burden on the healthcare system. In Pennsylvania (PA), chronic disease is the leading cause of death and disability, accounting for 80 percent of health care costs and hospitalizations. Due to the increasing cost of health care, many families, governments, businesses, and insurers have decided to limit health care services, and as a result only 56 percent of people with a chronic condition received evidence-based care that is recommended for their conditions.³

Chronic disease management, if adopted by health care providers and patients, will have long-term effects on health benefits for residents. As a result, there will also be economic benefits since healthier employees will mean improved productivity for the businesses as well as a reduced need for emergency room visits and lower insurance premiums. Diabetes is a chronic condition which affects the national and global populations as well. As one of the main causes of death in many developed countries, diabetes places a substantial burden on the world.³ The rates of type 1 and type 2 diabetes are climbing, making this disease one of the major challenges for healthcare professionals. The American Diabetes Association reports that there are 25.8 million children and adults in the United States, or 8.3% of the population, who have diabetes, and another 79 million with "prediabetes".⁴ A 2010 report states that 8.8% of Pennsylvanians have been told by a doctor they have diabetes, ranking the state eighteenth in the nation.⁵

Many researchers have found positive outcomes with the use of computers in disease education.⁶ Gustafson et al. found that computer-based patient education resulted in improved cognitive functioning and social support, in addition to an increase in life activities and more active

participation in healthcare. Further, with computer-based education, patients were more likely to call a doctor for problems, but physician office visits were less frequent and shorter in duration.⁸

Rural patients have higher rates of developing chronic illness and exhibit poorer health behaviors. There are many barriers to delivering care to rural communities, including: resource limitations, serving in a low-volume environment, challenges with recruiting health care professionals, and difficulty paying for and implementing necessary technology. Additional barriers to rural health care include: long distances to travel (30 miles +), inclement weather conditions, time, family and work commitments, economic barriers, and a large elderly population who are unwilling or unable to drive to central locations are key factors that prevent them from accessing existing resources.

Metabolic Syndrome

One of the main precursors of diabetes is a diagnosis of metabolic syndrome (MS). MS is defined as a grouping of interrelated risk factors that include elevated blood pressure and elevated plasma glucose levels. One theory states that insulin resistance is the main cause of MS, thus the high correlation of MS to type 2 diabetes mellitus. A previous study, based on information from the 2003-2006 National Health and Nutrition Examination Survey, estimated the prevalence of MS to be 34% of U.S. adults or 104 million people based on 2010 census data. People with MS are also believed to be at an increased risk for cardiovascular disease.

The key emphasis in the MS population is on the management of modifiable risk factors (including obesity, physical inactivity, smoking, and atherogenic diets) through lifestyle modifications. ¹³ However, with current trends in shortening the length of physician visits, there is not sufficient time to provide education on diet, exercise, and healthy behaviors. In this situation, education is most often the aspect of the office visit that gets disregarded. Patients are left without the knowledge they need to manage their condition at home. There is a need to provide reliable diabetes education to patients who experience the repercussions of time limitations in doctors' offices. Therefore, a goal in diabetes education is to provide patients with comprehensive disease education, without increasing the time of a physician's office visit. ¹⁴

Gestational Diabetes

Shaw et al. studied the interest and satisfaction of pregnant women who had access to online health information and records in Hamilton, Ontario. The two arm study provided pregnancy related information through a website and electronic access to antenatal records for enrolled subjects. Utilization data showed that women with access to personal information were much more active than the other group who only had access to general information. Pregnant women are believed to have more motivation to engage in positive health behaviors and providers spend a lot of time answering questions verbally with this population. With the growing trend of shorter clinical encounters, patients will most likely have questions they did not have time to ask during their visit. The researchers concluded that the pregnant population is prepared to use online health information to improve their well-being.¹⁵

Gestational diabetes (GD) is commonly defined as glucose intolerance first recognized during pregnancy and prevalence may be as high as 20% of pregnancies. Perinatal complications include hypertension, preterm birth and caesarian deliveries among others. Postpartum complications for the mother may include diabetes and cardiovascular disease. Monitoring of glucose levels, weight management, nutritional intake, physical activity and pharmacotherapy can reduce health problems during and after pregnancy. Although an acute condition, gestational diabetics may benefit from additional education and greater access to their providers. Gestational diabetics were added as an additional study arm in 2011.

Personal Health Records (PHRs)

President Barack Obama has provided a large infusion of funding towards transforming the health care delivery system through new investment in health information technology, such as electronic medical records (EMRs), electronic PHRs and health information exchange. Many stakeholders have become engaged with PHRs in the last few years, including consumers, hospitals/health systems, physicians, government (e.g. Department of Defense, Department of Health & Human Services (HHS), Medicare), insurance companies (e.g. Aetna), web companies (e.g. Google), employers (e.g. Wal-Mart), and information technology vendors. It remains to be seen if momentum can be maintained to have uniform standards to create a more efficient and less costly health care industry through wide PHR usage. 17

Electronic PHR adoption by consumers and providers has been slow in the United States due to varying factors. According to a 2008 consumer survey of 1,850 adults commissioned by the Markle Foundation, only 2.7% of U.S adults (6.1 million persons) utilize electronic PHRs. A more recent 2010 California Healthcare Foundation report states that only 7% of U.S. adults use some sort of PHR, with 51% of access offered by their health insurance plan 19. The most cited reasons for a lack of interest were concerns about the protection of medical information and how it would be shared. To combat such concerns, Connecting for Health, a public-private collaborative group engaging more than 100 organizations representing all major stakeholders of the healthcare industry, published a Common Framework for Networked Personal Health Information. This framework provides a roadmap for establishing trust among all participants and encourages the appropriate treatment of personal health information when electronically shared across various distinct networks. 20

Many PHRs have similar functions and services that enable consumers to manage their health by compiling their personal health information from varied sources (e.g. medications, lab results, allergies, surgeries, office visits, conditions, family histories, etc) in one place. Many popular PHRs are electronic, which makes them available anywhere and anytime there is an available connection to the Internet. This ease of access is especially important in an emergency situation, and could ultimately help save a life. Since the consumer controls the PHR, the following data may be added as well: food allergies, health conditions, over the counter/herbal medications, physician list, and emergency contacts.

Through secure messaging with their physician, patients can virtually ask questions about their health, saving them time away from work and traveling costs to the office as done traditionally.

Secure messaging can be extremely helpful in situations that involve non-urgent issues, which will likely free up time for office-based appointments with more serious issues. Primary-care office visits dropped 25% from 2004-2007 after Kaiser Permanente's Hawaii region offered secure messaging between providers and patients.²¹ A more recent patient-centered care initiative gaining momentum is called "Blue Button". It allows Veterans to download their personal health information from the Veterans Administration and share with their doctors.²² The concept has also been implemented by CMS for Medicare beneficiaries. It is likely the technology will penetrate the private sector and reach more patients in the coming years.

A Deloitte 2009 Survey of Health Care Consumers stated that 57% of respondents want a secure Internet site that would enable them to access their medical records, schedule office visits, refill prescriptions, and pay medical bills. Additionally, 55% of respondents are interested in email access with their doctor and 42% of respondents are interested in a PHR that is connected to their doctor's office. It is evident that electronic PHRs can help close the gap between consumers' expectations and what they are actually receiving from physicians.²³

PHRs may also help patients who struggle with chronic diseases through self-management tools. For example, some PHRs have preventive service reminders and educational materials that allow patients to better control their conditions through online tools (i.e. diabetes management).

Methods

The specific aims of this protocol were to develop an innovative approach in providing chronic disease health information to both a metabolic syndrome and gestational diabetes populations residing in a primarily rural geographical area and to evaluate subsequent effects on health outcomes. The primary objective was to assess any differences in health outcome measures (e.g. weight, glucose) between those who utilize the PHR (Relay Health was the specific product, see Figure 1) and those who continue using normal communication methods as part of the regular medical management of their condition (Control Group). Secondary objectives were to determine usage and satisfaction of PHR functionalities (e.g. secure messaging) from the patient and provider perspectives. Subjects in the PHR Group were provided with a customized instructional manual.

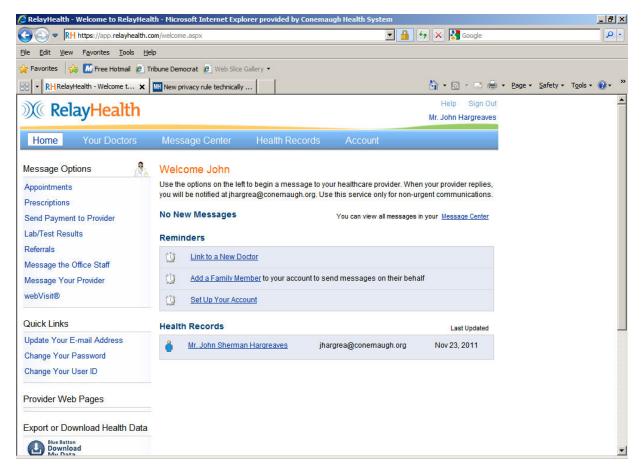


Figure 12. Relay Health Personal Health Record.

Hypotheses

MS Arm GD Arm There will be a significant difference in the There will be a significant difference in the following health outcome measures between following health outcome measures between the the PHR group and the Control Group: PHR group and the Control Group: **Blood Pressure Blood Pressure** HA1c Body Fat **Body Mass Index** Weight Glucose HA1c HDL Triglycerides Waist Circumference Weight

Study Design

The study team sought to enroll 100 subjects (MS arm) and 74 subjects (GD arm) in the study. Subjects were a sample of English-speaking patients who met inclusion criteria for the study (defined below). Subjects meeting inclusion criteria were randomized into one of two groups: a PHR Group or a Control Group. In addition, participating providers utilizing the PHR were asked to provide input through a survey instrument. The study enrolled subjects from 2010-2012.

Inclusion and Exclusion Criteria

MS Arm – Inclusion:

- Subject must meet three of the following five criteria as assessed by research staff to be included in the study:
 - Blood Pressure equal to or greater than 130/85 or the person is receiving pharmacologic therapy for hypertension
 - Waist circumference:
 - Men greater than 40 inches
 - Women greater than 35 inches
 - Triglycerides equal to or greater than 150 mg/dL or the person is receiving pharmacologic therapy for elevated triglyceride levels
 - Fasting Blood glucose equal to or greater than 100 mg/dL or the person is receiving pharmacologic therapy for elevated glucose levels
 - HDL Cholesterol:
 - Men less than 40 mg/dL
 - Women less than 50 mg/dL
- Subject must sign the informed consent document and HIPAA authorization
- Subject must commit to attend all three data collection points
- Subject must have Internet connectivity
- Subject must be willing to use the PHR and agree to its "Terms of Use"
- Subjects must be an established patient of a study physician
- Subject must be English-speaking and literate

MS Arm - Exclusion:

- Persons who are under 18 years of age
- Women who are pregnant, since metabolic syndrome in pregnancy is managed very differently than for other adults
- Persons who are not willing to sign the informed consent document and HIPAA authorization
- Persons who have no access to the Internet
- Persons who are not English-speaking and literate

GD Arm – Inclusion:

- Subject has gestational diabetes diagnosis confirmed by Conemaugh OB/GYN
- Subject must sign the informed consent document and HIPAA authorization
- Subject must commit to attend standard visits with physician and/or midwife
- Subject must have Internet connectivity
- Subject must be willing to use the PHR and agree to its "Terms of Use"
- Subject must be an established patient of a study physician and/or midwife
- Subject must be English-speaking and literate
- Subject must be 16 years of age or older

GD Arm – Exclusion:

- Persons who are under 16 years of age
- Persons who are not willing to sign the informed consent document and HIPAA authorization
- Persons who have no access to the Internet
- Persons who are not English-speaking and literate

Data collection

The research team used existing outcome measures from the previous MIDHT study to evaluate health outcomes of a metabolic syndrome population, including weight, BMI, waist circumference, body fat, blood pressure, Hemoglobin A1c, glucose, HDL and triglycerides. This was done to identify clinical outcomes of patients who were involved in the study. The team also used a technology evaluation to assess the comfort level and satisfaction of using a PHR, both from the patient and provider perspective.

Subjects enrolled in the gestational diabetes arm had their data retrospectively provided (by chart review) to the research team by Conemaugh OB/GYN staff. The data included weight and blood pressure at three time points (28-32 weeks, last visit before delivery and 6 weeks postpartum). In addition, oral glucose tolerance tests were conducted at two time points (28-32 weeks and 6 weeks postpartum). This did not apply to Hemoglobin A1c, which was ordered by the Principal Investigator at the time of screening, within 12 hours of delivery, and 6 weeks postpartum. Subjects in this arm were provided the same survey to assess satisfaction of the PHR.

Additionally, a chart review was conducted in which the following data was collected:

- ❖ Demographic information: age, race, and history of gestational diabetes were to have been analyzed for correlation with the outcome variables sample size did not permit this analysis.
- ❖ Weight and blood pressure at each standard of care clinical appointment post diagnosis of gestational diabetes were collected to calculate trends of these variables; the expanded dataset offering the potential for a higher degree of confidence of calculated statistical measures.
- ❖ Gestational age, baby weight and length, number of babies birthed, neonatal outcomes: through a nonparametric correlation analysis, these data were to have been used as additional indicators of the degree of control of subject gestational diabetes.

Data collection occurred according to the following table:

				r	'ime P	oint	
Participant	Approach ¹	Group ²	Instrument	1 (Baseline)	2	3	Monthly
Subjects	Both	All	Readiness to Change	X			
Subjects	Both	All	Concomitant Medication Log	X	X	X	
Subjects	Quant.	All	Data collection from Subject Charts and Lab work	Х	X	X	
Physicians	Both	All	PHR Survey			X	
Subjects	Both	I	PHR Survey			Х	
Subjects	Both	All	Outside Study Exposure	X	Х	Х	
Both	Quant.	I	Usage Report				X
Subjects	Both	All	Internet Usage Assessment	X			

Note 1: Approach = qualitative (Qual.), quantitative (Quant.), or Both

Note 2: Group = I for Intervention, All for both Intervention and Control Groups

Table 18. Data Collection Schedule.

Readiness to Change Instrument

A readiness to change tool was completed by each subject prior to beginning the study. The tool is based on the Transtheoretical Model (TTM), proposed by Prochaska and DiClemente in 1983. The model of behavior change has been used to create effective interventions that promote health behavior changes. TTM focuses on each individual's decision making and involves emotions, cognition, and behavior. The TTM describes basic Stages of Change in which individuals identify themselves based on their current status and readiness to change.²⁴

The results of the readiness to change scale were compared to the final outcomes of the study, to determine if there was a correlation between each subject's readiness to change their diet and exercise and the actual outcomes that are made as a result of the study.

PHR Patient Survey

Subjects in the PHR Group were asked for their individual input regarding their satisfaction and usage of the personal health record used during the study. The survey was mainly based upon questions provided by Relay Health, which have been used previously with patients on a national level. Relay Health provided their permission to use the survey questions. Subjects completed the survey at the end of their participation. The survey was created in "Survey Monkey" and was made available to subjects online.

PHR Provider Survey

Study physicians were asked for their written input regarding their satisfaction and usage of the personal health record used during the study. The survey was mainly based upon questions provided by Relay Health, which have been used previously with physicians on a national level. Relay Health provided their permission to use the survey questions. The survey was created in "Survey Monkey" and was made available to providers via interoffice mail.

Outside Study Exposure

All subjects were asked to describe their exposure to education (e.g. websites) and resources (e.g. office-based physician visits) regarding their metabolic syndrome or gestational diabetes condition "OUTSIDE" of the PHR during the study period using an internally developed instrument. Additionally, subjects provided information on their exercise and nutrition habits. The information collected was used for control purposes to help analyze the true impact of the PHR.

Medication Log

Subjects were asked to provide a list of their medications (e.g. name, dosage, start date and/or end date) during all study visits. The self-reported information was documented by study coordinators. This information is part of the subjects' medical history and may have potential effects on outcome measures (e.g. blood pressure, lipids levels).

PHR Usage Report

PHR usage for each specific subject was manually collected by the Associate Investigator via the Relay Health application on a monthly basis. He had administrator access and viewed the provider/subject communications and blood glucose input data to perform simple message counts and health record completion. This information was used to support the secondary objective of determining which functionality was used and how often by study stakeholders.

Internet Usage Assessment

An internally developed questionnaire was deployed to assess subjects' usage on the Internet before the study commenced. Results helped the study team determine internet usage, what online activities were being performed, their experience with online health/medical information, and previous usage of an electronic personal health record.

Recruitment/Enrollment

In order to generate patient interest in the study, Conemaugh staff used various recruiting strategies during the study period, including:

- Direct patient letters
- Advertisements in numerous newspapers
- Facebook postings
- Flyers and posterboards in participating physician offices
- Phone On Hold messages
- Global emails
- Face-to-face meetings with physicians
- Community health fairs
- Metabolic syndrome lectures
- Direct-to-consumer study introduction

Subject recruitment for the respective study was challenging. Interest for the MS arm was greatest from patients deriving from primary care suburban physician offices however anecdotal concerns persist regarding Internet access and a high elderly population in rural communities. Additional sites were added to the study with the goal of increasing enrollment. These included the Johnstown Free Clinic (patients without health insurance) and the Conemaugh Weight Management Center (patients involved in a structured program). Overall, interest from these populations was minimal and compliance was an issue as well. A total of 66 subjects were enrolled in the MS Arm with 45 subjects completing the study.

Over 40 patients with GD were approached by physicians and research staff about participating in the study. Unfortunately a large majority of patients were not interested in participating as only five (5) subjects were enrolled in the GD Arm with 3 subjects completing the study. This population was likely consumed with their new diagnosis and current condition leading to their

general feeling of not wanting to add additional responsibilities to their life. A current literature search did not yield any research studies involving the pregnant population and PHRs.

The following table describes study enrollment, including inquiries, screenings, number of enrolled, number of withdrawals and number of subjects completing the study.

Study Enrollment Summary

Description	Study Arm:>	GD	MS
Inquiries		40	160
Screenings		5	78
Screen Failures		0	12
Withdrawals	<u> </u>	2	19

Enrolled:	5	66
Completed (see NOTE):	3*	45*

(combined sums for both Study Arms) Totals									
Study Group (by randomized group assignment):>	Control:	PHR:							
Completed (at least chronologically):>	19	29							

* NOTE:

A completed subject is defined as one that both chronologically completed the study and on which complete data exists per the protocol design.

The data completeness varies both by subject and variable (e.g. survey question response, physical measurement, lab value, etc.); this fact naturally leads to the potential for differing but appropriate and valid sample sizes for each conducted analysis.

Table 19. Study Enrollment Summary.

Results and Data Analysis

Disposition of Study Hypotheses:

MS Arm

This hypothesis is rejected for all outcome measures except blood pressure.

Inherent in the study hypotheses was that the access and subsequent use of a PHR would improve the outcome measures for the PHR group to a greater degree than any improvement observed in the Control group. In spite of both groups remaining sufficiently consistent over time on the assessed potential confounders and statistical significance for blood pressure, two realities of the study, (1) the confounding of the PHR group due to the influence of medication changes during the study; (2) an extremely low PHR usage, require complete rejection of the study hypothesis. Although 47 subjects chronologically completed, data from one subject (Control group) was deficient to a degree that rendered it unusable for analysis on any of the outcome measures. One subject (Control group) had data for lab values but not physical measurements. Therefore, the final maximum sample size available for analysis consisted of either 45 or 46 subjects, depending upon the outcome measure.

GD Arm

This hypothesis could not be tested due to a very small sample size (due to data incompleteness, N=3).

Demographics by Study Arm and Study Group:

Gender * Group * Study Arm Crosstabulation

Age category * Group * Study Arm Crosstabulati	on
--	----

Count					
			Grou		
Study Arm			Control	PHR	Total
Gestational	gender	Female	2	3	5
Diabetes	Total		2	3	5
Metabolic	gender	Female	19	22	41
Syndrome	gender	Male	12	13	25
Cyriaionie	Total		31	35	66

Count					
			Grou	лр	
Study Arm			Control	PHR	Total
Gestational Diabetes	۸۵۵	16 - 29 years	1		1
	Age category	30 - 39 years	2	1	3
		40 - 49 years		1	1
	Total		3	2	5
		16 - 29 years	2	1	3
		30 - 39 years	3	4	7
Metabolic	Age	40 - 49 years	6	7	13
Syndrome	category	50 - 59 years	10	11	21
Syndronie		60 - 69 years	8	9	17
		70 yrs and older	2	3	5
	Total		31	35	66

Table 20A. Gender Demographics.

Table 20B. Age Demographics.

Results of Within and Between-Group Analysis of Outcome Measures:

The outcome measures (physical measurements and lab values) were analyzed using a repeated measures analysis of variance (RM-ANOVA) over the three time points (baseline [1], three months [2], six months [3]) on a within and between-group basis. The family-wise alpha was set at 0.05 and the Sidak correction was used to adjust for multiple comparisons. The groups being assessed were Control and PHR. Computation of inferential statistics was only possible for the MS Arm of the study. The GD Arm contained only five subjects – only three with nearly complete data.

Calculations for the MS arm produced the following:

Within-Group Results (N = 46, maximum):

For the Controls, the within-group results showed no statistical significance on any of the outcome measures. The results for PHR showed statistical significance on waist circumference (inches), weight (lbs.), and BMI only. Pairwise comparisons revealed the statistically significant change to be between baseline and six months. For all three variables, the direction of change was negative (last minus first) and indicates an improvement of the outcome measure.

Variable	N, Control // N, PHR	Multivariate p-value	Mauchly's Test	Epsilon Corrected p-value, Greenhouse-Geisser	Pairwise p-value	Mean Diff., (6 mos. – baseline)
waist circumference	18 // 27	0.012	Passed	N/A	0.011	-1.390
weight	18 // 27	0.041	Violated	0.010	0.032	-4.977
BMI	18 // 27	0.053	Violated	0.014	0.043	-0.737

Table 21. Within-Group p-values.

Between-group Results (N = 46, maximum):

The between-group (between Control and PHR) results showed no statistical significance on any of the outcome measures except for both the systolic and diastolic blood pressure values. On average, the PHR group diastolic and systolic pressures were less than the Control group by -11.6 mm HG and -5.4, respectively. Box's Test held for both variables and the p-values were 0.006 and 0.005, respectively. For these outcome measures the sample sizes were 18 (Control) and 27 (PHR). The following graphs depict the change of these variables over time by group.

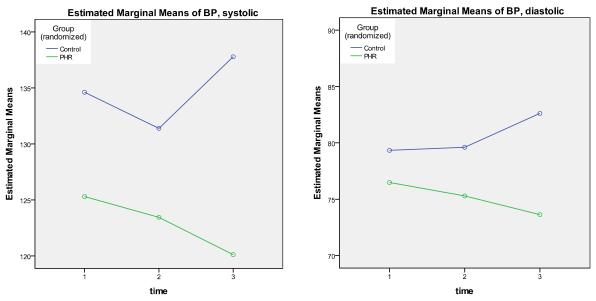


Figure 13. Estimated Marginal Means of Blood Pressure, systolic and diastolic.

Calculations for the GD arm follow:

Although inferential statistics are non-calculable for the GD arm due to insufficient sample size, the change or delta between time points (delta equals as described in the 'where' section found on the following tables) for the five subjects over the outcome measures does provide some useful information. Of course, extrapolation to any group or population-wide conclusions is not feasible. The raw data has been provided for additional clarity.

The delta for the outcome measures for the five available subjects are as follows:

			Delt	as			Raw Data					
variable name:>>	BP_s_ 7_1	BP_d_ 7_1	wt_7_1	HA1c_ D_S	HA1c_ P_D	HA1c_ P_S	BP_s_ 1	BP_s_ 7	BP_d_ 1	BP_d_ 7	weight_ 1	weight_ 7
	28	16	-13.0	-0.2	NC	NC	96	124	64	80	187	174
	-2	-16	-24.5	0.1	0	0.1	104	102	76	60	174	150
	-16	0	-13.5	0	0.4	0.4	112	96	60	60	143	130
	-2	8	-13.5	-0.1	0.2	0.1	102	100	60	68	204	190
	-10	-14	-22.5	0.3	NC	NC	110	100	78	64	204	181
mean	-0.4	-1.2	-17.4	0.0	0.2	0.2	104.8	104.4	67.6	66.4	182.2	164.8
std. dev.	16.935	13.828	5.617	0.192	0.200	0.173	6.419	11.171	8.764	8.295	25.171	24.811
min	-16	-16	-24.5	-0.2	0	0.1	96	96	60	60	143	130
max	28	16	-13	0.3	0.4	0.4	112	124	78	80	204	190

Table 22. Gestational Diabetes Arm Outcomes Measures, deltas and raw data.

			Rav	w Data			
variable name:>>	HA1c_0_ Screening	HA1c_1_ Delivery	HA1c_2 _Post	Baby Weight_ lbs	Baby Length_ inches	OGT_ 2hr	OGT_ 3hr
	4.9	4.7	М	8.375	21.0	М	120
	5.1	5.2	5.2	6.625	19.0	86	167
	5.2	5.2	5.6	5.750	19.0	М	М
	6.0	5.9	6.1	6.438	19.5	187	М
	5.3	5.6	М	6.313	19.0	73	М
mean	5.3	5.3	5.6	6.700	19.5	115.3	143.5
std. dev.	0.418	0.455	0.451	0.992	0.866	62.405	33.234
min	4.9	4.7	5.2	5.750	19.0	73	120
max	6	5.9	6.1	8.375	21.0	187	167

Table 23. Gestational Diabetes Arm Outcomes Measures, raw data continued.

where:

NC = not computable M = missing
BP_s: systolic blood pressure, mmHG wt: weight, lbs.

BP d: diastolic blood pressure, mmHG HA1c: Hemoglobin A1c

OGT: Oral Glucose Tolerance Test

7 refers to the 6 month time point and 1 to the baseline time point S refers to screening, D to At Delivery, and P to six weeks postpartum

These calculations show signs of a generally decreasing trend (improvement) over all the outcome measures except delta HA1c between the post and screening time points. HA1c shows the opposite, an increasing trend. However, the increasing trend does not place any subject within the range considered to be clinically diabetic.

Regarding Subject Medications:

Information regarding prescribed medications was complete for the same 45 subjects that had *complete* data for *all* outcome measures. For this analysis, complete refers to (the existence of) data at both the beginning and end of the study. Relative to the beginning and end of the study, these subjects were categorized as having a net medication change or not. Medication information was self-reported by subjects without any insight regarding medication adherence.

General Medication Class:	Hyper	tensive	Lipid L	owering	Glucose Control					
Study Time point:	Baseline	6 months	Baseline	6 months	Baseline	6 months				
Subjects Identified as having NO net medication change from the start to the end of the study N, Control = 15; N, PHR = 19										
Count of subjects with at least one med.	23	23	23	23	8	7				
Count of subjects	34	34	34	34	34	34				
% of subjects with at least one med.	68%	68%	68%	68%	24%	21%				
Average of Baseline & 6 mo.	68	3%	68	3%	22%					
Subjects Identified as having a net r N, _{Control} = 3; N, _{PHR} = 8	nedicatio	n change f	rom the s	tart to the	end of th	e study				
Count of subjects with at least one med.	10	7	6	5	8	7				
Count of subjects	11	11	11	11	11	11				
% of subjects with at least one med.	91%	64%	55%	45%	73%	64%				
Average of Baseline & 6 mo.	77	7%	50)%	68%					

NOTE: Total N, Control = 18; Total N, PHR = 27; Total N for this analysis = 45

Table 24. Categorical Medication Analysis.

The details of the 11 subjects identified as having a net medication change are:

The Control Group details:

- one subject eliminated only lipid lowering medication,
- one subject eliminated one glucose control medication, and
- one subject eliminated two (all) glucose control medications.

The PHR Group details:

- four subjects eliminated one hypertensive medication
 - o three reduced from one to none
 - o one reduced from two to one
- one subject added a hypertensive medication
- one subject added a lipid lowering medication
- one subject eliminated one of three glucose control medications
- one subject added two glucose control medications

Obviously medication changes could have confounded the study results since, if effective, the medications alone could cause or at least contribute to any observed change in the outcome measures, particularly the lab values. Given this truth, the question then follows as to whether the percentage of those subjects with a net change was sufficient to impact the between group

analysis. Given 30% of the PHR group had a net medication change, a confounding influence can reasonably be presumed to have existed.

PHR Usage Summary:

Twenty nine subjects assigned to the PHR group actually utilized the application. Irrespective of study completion, forty subjects were assigned to the PHR group. Ten did not finish participation in the study. Of the thirty subjects in the PHR group that finished, 28 used the PHR. One non-finisher from the GD arm did have usage data and an equivalent time of opportunity for usage (three months) as the one other GD arm subject that did finish the study and was included in this analysis. All subjects had a six month time frame in which to use the PHR. The following table represents the sum of unique activity (total usage) for all subjects by message type and health record section.

N, total:		Health Record Data Types							Secure Messaging Data Types					
29 subjects	PHR_ Meds_ Algs	PHR_ Fam_ Soc_ Hx	PHR_ Probs _Proc	PHR Results	PHR_ Imuz	PHR_ Vitals	PHR_ Files	PT_MSG _Rx_Refl _Req	PT_MSG _N2D	PT_MSG _TL_Res _Req	PT_MSG _Admin	PT_MSG_ Apt_Req	PT_MSG _PT_Init_ webV	PT_MSG _Ref
SUM	22	13	10	7	7	1	1	18	12	11	6	3	1	0
percentage	36%	21%	16%	11%	11%	2%	2%	35%	24%	22%	12%	6%	2%	0%
cumulative percent	36%	57%	74%	85%	97%	98%	100%	35%	59%	80%	92%	98%	100%	100%

Health Record Data Types			Secure Messaging Data Types		
Variable Name	Description		Variable Name	Description	
PHR_Meds_Algs	Meds and Allergies		PT_MSG_Rx_Refl_Req	Rx Refill Request	
PHR_Fam_Soc_Hx	Family & Social History		PT_MSG_N2D	Note to Doc	
PHR_Probs_Proc	Problems and Procedures		PT_MSG_TL_Res_Req	Test/Lab Results Request	
PHRResults	Results		PT_MSG_Admin	(general) Administration	
PHR_Imuz	Immunizations		PT_MSG_Apt_Req	Appointment Requests	
PHR_Vitals	Vitals		PT_MSG_PT_Init_webV	Patient-Initiated webVisits	
PHR_Files	Files		PT_MSG_Ref	Referrals	

Table 25. Personal Health Record Usage.

Patient PHR Survey Summary:

The following tables highlight that the subjects had a positive PHR experience: 88% were satisfied or very satisfied; 88% perceived PHR to be secure & confidential; 46% said they would continue to use a PHR after the end of the study. Also, 66% accessed the PHR from home and 76% used a DSL internet connection. Recall, not all subjects eligible to respond to this survey instrument did so; and not all of those who responded, answered every question. Therefore the total response (sample size) per question varies.

Age category * gender Crosstabulation

Age category * Overall Satisfaction of Relay Health Crosstabulation

Count

age category	ger		
age category	Male	Female	Total
18 - 29 years	0	1	1
30 - 39 years	1	3	4
40 - 49 years	1	4	5
50 - 59 years	1	7	8
60 - 69 years	2	3	5
70 yrs or older	1	1	2
Total	6	19	25

Count						
age category	Overall Satisfaction with the Relay Health service					
age category	Very Satisfied	Satisfie d	Dissatisfied	Total		
18 - 29 years	0	1	0	1		
30 - 39 years	1	3	0	4		
40 - 49 years	5	0	0	5		
50 - 59 years	2	4	2	8		
60 - 69 years	3	1	1	5		
70 yrs or older	1	1	0	2		
Total	12	10	3	25		

The answer choice, very dissatisfied, was not chosen by any respondent.

Table 27. Age*overall satisfaction crosstab.

Table 26. Age*gender crosstab.

Crosstab

Did you feel your medical information and personal communications were secure and confidential over the Internet?

Count			
age category	Yes	Not Sure	Total
18 - 29 years	1	0	1
30 - 39 years	4	0	4
40 - 49 years	5	0	5
50 - 59 years	7	1	8
60 - 69 years	3	2	5
70 yrs or older	2	0	2
Total	22	3	25

The answer choices, 'no' and 'I had problems', were not chosen by any respondent.

Table 28. PHR Security & Confidentiality.

Crosstab

A Personal Health Record (PHR) allows you to organize and store all of your health and medical information in one convenient location. Will you continue using a PHR after the study is over?

Coun

age category	Yes	No	Not Sure	Total
18 - 29 years	0	0	1	1
30 - 39 years	2	0	2	4
40 - 49 years	3	0	1	4
50 - 59 years	5	1	2	8
60 - 69 years	1	1	3	5
70 yrs or older	0	0	2	2
Total	11	2	11	24

Table 29. PHR Usage Post Study.

Crosstab

C	ΩI	J٢	٦t

	In v	vhat ways has	Relay He	alth he	elped yo	u? (check	all that apply	/)
age category	Gave me greater access to my doctor/staff	Improved communication with my doctor	Easier to obtain medication refills	Saved me time	Easier to obtain lab/test results	Easier to obtain my medical information	My questions and concerns were addressed more quickly	Improved my medical care
18 - 29 years	1			1				
30 - 39 years	1		3	2	1	1		1
40 - 49 years	2	2	2	2		1	1	1
50 - 59 years	4	3	4	1	3	2		
60 - 69 years	4	5		1	4	1	2	
70 yrs or older			1	1		2		
Total	12	10	10	8	8	7	3	2

Table 30. PHR Benefits – Patient Perspective.

Provider PHR Survey Summary:

Five providers responded to the survey but did not complete all questions.

Recall, not all providers eligible to respond to this survey instrument did so; and not all of those who responded, answered every question. Therefore the total response (sample size) per question varies.

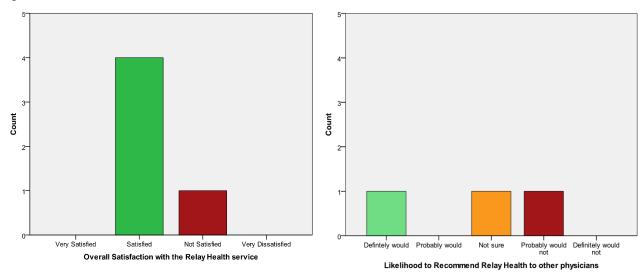


Figure 14. Provider Perceptions of Relay Health.

Which of the following Relay Health features were most valuable to your practice?

			-				
N	webVisit	Patient health record	Send education/ resources to specific paitent populations	Note to doctor	Send lab/ test results to patients	Appointment scheduling	
Valid	0	0	0	2	4	1	
Missing	5	5	5	3	1	4	
Sum				2	4	1	

How has Relay Health benefited your medical practice?

N	Enhanced QoC through improved communication with patient	Improved patient satisfaction	Improved office efficiency	Increased time for patient care	Enhanced patient care due to access to accurate info.	Improved office staff - physician communication	Decreased telephone call volume	Reduced unnecessary office visitis
Valid Missing	2	0	0	0	0	0	0	0
SUM	3 2	5	5	5	5	5	5	5

Table 31. Clinical Benefits of PHR – Provider Perspectives.

Readiness to Change:

An independent t-test was attempted for a between arm (GD vs MS) analysis by considering the answer choices to both questions of the Readiness to Change Survey as interval data types. The first question asks about the subject's current physical activity status and the second about current diet status. The answer choices for both questions are coded from 1 to 5 with the following designations:

1 = pre-contemplation 3 = preparation 5 = maintenance 2 = contemplation 4 = ACTION

The MS, N = 66, sample size is approximately 13x that of GD, N = 5. This sample disparity violates symmetry assumptions and contributes to issues arising from heterogeneity of variance. Levene's Test is violated for current Diet Status. Both questions violate normality. Despite these issues, the difference between the group means of current diet status yields a statistically significant p-value of 0.005 at alpha = 0.05. However, this finding should be viewed with extreme caution given the aforementioned issues. As such, a Mann-Whitney U test was performed and revealed no statistical significance for either question and thereby substantiated that the violations are too severe for application of analysis by parametric algorithms.

Internet Usage Survey:

Collectively, the following graphs demonstrate sufficient similarity between Control and PHR groups by study arm regarding computer and internet browsing experience, internet usage (time/day), and location of said use, such that homogeneity, at least on these parameters, is presumed to have existed. Also, the total count of surveyed internet activities over the six month period is fairly normal.

Sample Size Summary

Variable Description	Control Group	PHR Group	Study Arm
Computer Experience Internet Browsing Experience Count of Unique Internet Activities	3	2	GD
Internet Usage/day – Personal Internet Usage/day – Work/Business	30	35	MS

NOTE:

- The total N for either study arm does not exceed enrollment for that arm
- Data was missing for one subject that did not finish the study
- Usable data was present for some subjects that did not finish the study

Table 32. Sample Size for Internet Usage. Survey.

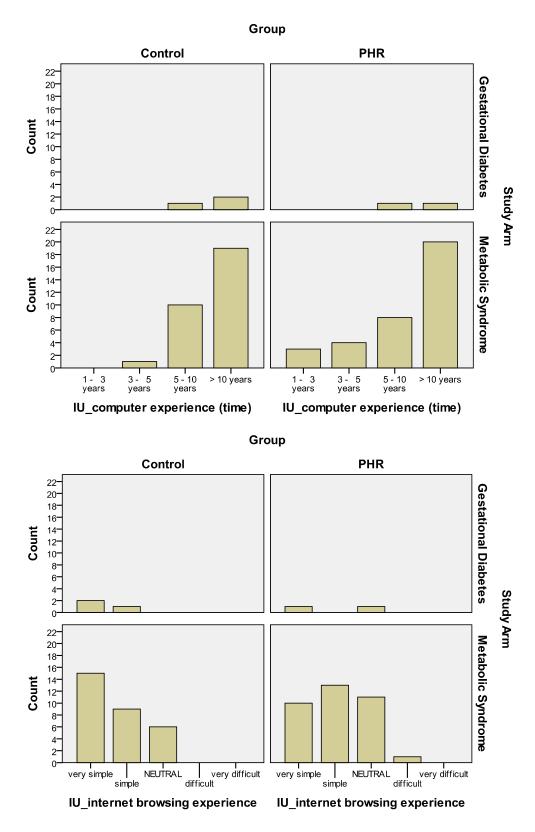


Figure 15. Computer and Internet Browsing Experience.

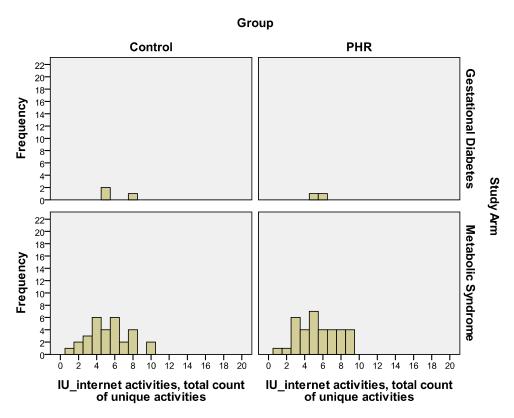


Figure 16. Histogram of Unique Internet Activities.

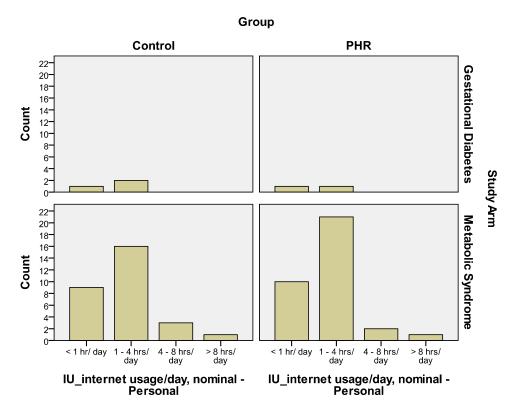


Figure 17A. Internet Usage – Personal.

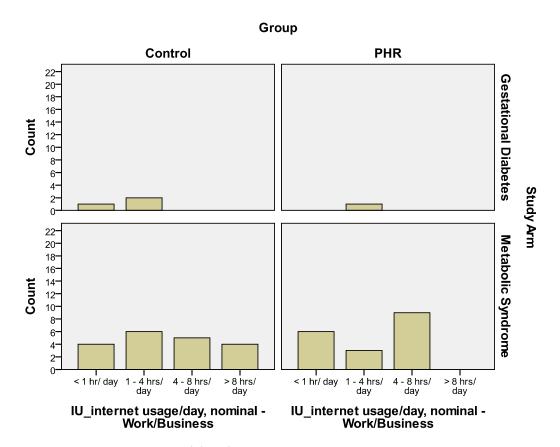


Figure 17B. Internet Usage – Work/Business.

Outside Exposure Survey:

The following questions, or sums therein, from the Outside Exposure Survey were analyzed using a RM-ANOVA over six contiguous months (this survey was to be completed every month) on a within and between-group basis. The family-wise alpha was set at 0.05 and the Sidak correction was used to adjust for multiple comparisons. The groups being assessed are Control (N = 15) and PHR (N = 23). Computation of inferential statistics was only possible for the Metabolic Syndrome Arm (MS) of the study. The Gestational Diabetes Arm (GD) contained only five subjects - three with complete data.

- Q01: (sum therein): Total count of unique education resources by month
- Q02: Categorized number of websites visited, variable treated as interval
- O03: Categorized current exercise habits, variable treated as interval
- Q04: (sum therein): The sum of unique dietary changes by month

No statistically significant change over time (within group) or between groups was found. Because some of the variables were presumed interval and not scale as is preferred for RM-ANOVA, the within-group analysis was also accomplished using the Friedman Test. Those results did not change the conclusions drawn from the RM-ANOVA analysis. Note that currently a non-parametric equivalent to a between-group RM-ANOVA does not exist.

Therefore, stability over time and between groups was presumed to have existed for the outside exposure variables and as such produced no confounding influence on the study analysis.

Discussion

When compared to previous published studies on PHR usage, our experience with recruitment challenges during this prospective pilot research study was likely unique due to our small, rural geographic service area. The number of prospective studies analyzing PHR usage within a similar organizational and geographic scope to ours is quite limited. For organizations of similar size and scope, testing PHRs prior to wide deployment is a critical success factor; our experience indicates that both process and organization behavioral changes will probably be warranted in order to improve interest from subjects and providers alike. Future research should focus attention on the current state of health information technology implementation within the organization as this will impact provider willingness and support. Simply, the wider the gap between the current state and one with a fully functioning and highly utilized HIT implementation will inform to the barriers and guide the transformation. Participation in our study and usage of the Relay Health application by providers was directly influenced by the implementation of electronic health records (EHR). As the nation focuses on "meaningful use" stage 1 requirements for EHRs, consumer-facing technology is not a priority for many healthcare organizations at this time. In reality, the implementation and support of PHRs is likely five years away as support for it from additional "meaningful use" criteria for patient-centric initiatives materializes. Multiple issues still need to be resolved regarding PHRs, including provider reimbursement, service costs, data ownership and accuracy, security of PHI online, response time expectations, etc.

Successful PHR applications and portals available from large insurance companies, medical centers and the Department of Veterans Affairs (e.g. myHealtheVet) have built-in incentives for subjects to participate. These include efficient tethered access to scheduling and clinical data contained within the electronic health record (in addition to secure messaging), wellness reminders based upon age and gender and email alerts about upcoming appointments. Health summaries are also a valuable tool that you can share with a new doctor. Implementers should decide on their primary objectives and determine if they will purchase an off-the-shelf product (e.g. Relay Health) or develop internally. Attitudes and perceptions may be drastically different in the private sector compared to a military/veteran setting. PHRs may produce benefits as a communication tool but may have little impact on management of conditions and related outcomes measurements as the results of our study suggests.

Another area of concern is technology comprehension by subjects. As you work with subjects who have varying levels of education and literacy and technical experience, providers must understand that "one size does *not* fit all." Our experience showed that despite providing a detailed, written User Manual (at or below 8th grade level) to all subjects in paper and electronic form, some subjects did not comprehend how to use certain functionality (e.g. webVisit) and therefore did not utilize the application to its fullest extent. Subjects were also hesitant to ask for help or contact the vendor if they had questions or problems. However, subjects overwhelmingly did feel their health information was secure online (88%). This finding is opposite of a frequent

criticism of PHRs in general.

The three year study clearly highlighted a general lack of interest in PHRs by subjects, regardless of condition, in our geographic area as highlighted by persistent recruitment challenges and system usage. Various strategies were used to garner interest with little success, which aligned with provider disinterest. For those subjects that had a chance to utilize the technology, very few used it as a self-improvement tool to enhance access to their healthcare team and to utilize online educational resources. PHRs potentially may benefit medication adherence through greater self-monitoring of lab results, efficient medication refills and greater access to providers through secure messaging. Our findings generally align with other studies that experienced limited PHR use and had a difficult time associating usage with improved health outcomes.²⁵⁻²⁶

Study Closure

Study enrollment was closed on September 24, 2012. This was done in order to complete data collection, data analysis and write-up of results before the contract end date of January 31, 2013.

KEY RESEARCH ACCOMPLISHMENTS

- Northrop Grumman support of White House mandated Virtual Lifetime Electronic Record (VLER) 1a project in San Diego, CA
- Northrop Grumman contribution of document assembler code to the FHA CONNECT release v2.4; Conemaugh contribution of Allscripts adapter code
- Successful bi-directional health information exchange (using test data) between
 Department of Defense and Conemaugh utilizing the NwHIN model
- Full disclosure of technical documentation and code (source/binary) to TATRC
- The following table summaries NG deliverables that have been completed

No.	Title	Due Date
4	Demonstration of Electronic Exchange of Test Allscripts CCD via CHS Portal	Completed 4/1/2010
5	Technical and Functional Requirements – Phase II	Completed 2/23/2010
6	Technical Feasibility Study – Migrating AHLTA/BHIE Web Services Towards NHIN	Completed 9/30/2009
7	NHIN Background/Gap Analysis	Completed 2/22/2010
8	Migration Plan for Movement from Viewable (Textual) Data to Computable Data	Completed 1/15/2010
9	Electronic Patient Consent Assessment Report	Completed 9/30/2009
10	Demonstration of the NHIN Adaptor With One Site	Completed 4/1/2010
11	Assist with DURSA Submission	Completed 1/21/2010
12	Disclosure of Technical Specifications	Completed 4/3/2010
13	Checklist of Criteria Met/Unmet Necessary to Meeting HIE Accreditations and Certifications	Completed 3/12/2010
14	MIDHT Portal Test Plan	Completed 3/19/2010
15	Inventory List	Completed 1/25/2010
16	VLER Code Drop to FHA/DHIMS	Completed 1/18/2010

Table 33: Northrop Grumman Deliverables.

- Completion and closure of study A 15835.2
- Completion and closure of study A 16192.1
- Completion of study A −15835.1, closure documents sent to CMMC IRB

REPORTABLE OUTCOMES

- Conemaugh presented MIDHT project at a TATRC-sponsored workshop at St. Francis University on September 3, 2009.
- John Hargreaves' presentation on personal health records at the Cambria-Somerset Council Aging Conference Champion, PA on October 29, 2009.
- Health Information Exchange Demonstration @ HIMSS Atlanta, GA (March 1-3, 2010).
- John Hargreaves' presentation on personal health records at the Cambria-Somerset Council Conference at the Slopes in Champion, PA on March 5, 2010.
- John Hargreaves and Charlie Shaw presented the MIDHT project at the TATRC Product Line Review in Frederick, MD on March 23, 2010.
- MIDHT studies highlighted at the 6th Annual Conemaugh Research Poster Symposium Johnstown, PA on March 22-26, 2010.
- Northrop Grumman contribution of the "document assembler" code to the nationally available FHA CONNECT release 2.4 (open-source).
- Virtual Lifetime Electronic Record 1a project tasks completed by Northrop Grumman.
- Allen Barger's presentation at the CONNECT Code-A-Thon in Miami, FL on April 28-29, 2010.
- Joe Dado and John Hargreaves presented at the TATRC Product Line Review on March 15, 2011 in Falls Church, VA.
- MIDHT studies highlighted at the 7th Annual Conemaugh Research Poster Symposium Johnstown, PA on March 28 – April 1, 2011.
- Conemaugh presented research update to Dr. Steve Steffensen and Betty Levine during local site visit in Johnstown, PA on June 9, 2011.
- MIDHT studies highlighted at the 8th Annual Conemaugh Research Poster Symposium Johnstown, PA on March 26-30, 2012.

	DoD Adapter	Conemaugh Adapter
Jar Files	Dob Huapter	Concinuign Function
	AdapterDocumentAssemblyProxyEJB.jar	AdapterDocumentAssemblyProxyEJB.jar
	BOSServiceEndpointProviderEJB.jar	BOSServiceEndpointProviderEJB.jar
	AdapterCommonDataLayerEJB.jar	•
	DocumentManagerEJB.jar	DocumentManagerEJB.jar
	DocumentRepositoryEJB.jar	DocumentRepositoryEJB.jar
	DoDConnector.jar	CHSConnector.jar
	MpiEJB.jar	MpiEJB.jar
	NHINAdapterServiceEJB.jar	NHINAdapterServiceEJB.jar
	NhincHL7JaxbLib.jar	NhincHL7JaxbLib.jar
Properties Files		
	Adapter_common_datalayer.properties	
	Adapter.properties	Adapter.properties
	DoD_connector.properties	CHS_connector.properties
	Repository.properties	Repository.properties
SQL Scripts		
	Docassembly_dll.sql	Docassembly_dll.sql
	Docrepository_dll.sql	Docrepository_dll.sql
	Templatedb_dll.sql	Templatedb_dll.sql
WSDL Files		
	BOSServiceEndpointProvider.wsdl	BOSServiceEndpointProvider.wsdl
	AdapterCommonDataLayer.wsdl	
	DocumentAssembly.wsdl	DocumentAssembly.wsdl
	DocumentManager.wsdl	DocumentManager.wsdl
	DocViewerRequestServicesService.wsdl	DocViewerRequestServicesService.wsdl
	DoDConnector.wsdl	CHSConnector.wsdl
WAR Files		
	UniversalClientGUI.war	UniversalClientGUI.war
	UniversalClientWS.war	UniversalClientWS.war
XML Files		
	adapterServicesMappings.xml	adapterServicesMappings.xml
XSL Files		
	CCD.xsl	CCD_CHS.xsl
Allscripts Folders		
		allscriptsdataset
		soapextender
		webservices

Table 34. MIDHT Code Delivered to TATRC/DHIMS/FHA.

CONCLUSION

MIDHT implemented and analyzed various health information technologies throughout Conemaugh Health System for the respective contract. Technologies were envisioned to assist both providers and patients in the journey to improve care coordination, workflow, duplicate testing and rising costs. The final results were mixed as major new investments take time to mature and the impact on people must be well planned and communicated effectively.

Our experience demonstrated that EHR systems produce many benefits to users but may also create new problems. Moving from a primarily paper-based record system to an electronic environment is complex and there will be bumps along the way. Implementers must not only focus on the technical product itself but also must plan accordingly during transition times and determine how work redesign will impact staff. It will be of great importance to set staff expectations in advance and keep communication lines open during the implementation process.

As providers implement EHR systems spurred by meaniungful use stimulus funding and thus have clinical data residing in electronic form, interoperability between systems becomes achievable and critically important in improving continuity of care and reducing costs. MIDHT provided valuable technical resources to assist the Department of Defense in achieving milestones for the Virtual Lifetime Electronic Record (VLER) 1a project in San Diego, California. Furthermore, valuable experience was gained by Conemaugh and Northrop Grumman staff with the CONNECT software, CDA specifications, CAL architecture, and C32 dynamic document generation which laid the framework for Conemaugh to become the first non-governmental institution in the state of Pennsylvania to become a production member of the Nationwide Health Information Network during a subsequent MIDHT award.

The implementation of PACS technology allows providers in disparate geographic locations to access images (for multiple modalities) performed off-site and encourages consultation between referring and receiving institutions. The implementation of PACS is especially valuable in a rural healthcare system such as Conemaugh consisting of an urban flagship medical center and two small hospitals. The reduction in unnecessary duplicate testing will continue to increase as more physicians embrace said technology and begin to change ordering habits.

PHR's have generated minimal interest and usage by subjects and providers to date. Our findings align with patient attitudes nationwide. Adoption of said technology remains below 10% and significant usage can only be found in geographic pockets or within specific patient populations. As the nation is currently focused on "meaningful use" of EHR systems, widespread adoption of PHRs may be five years away from reality.

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Appendix 1 - Electronic Health Record (EHR) Implementation Survey

1. The instructions and prompts are helpful.			
Answer Options	Response Percent	Response Count	
Never	12.0%	3	
Sometimes	52.0%	13	
Occasionally	4.0%	1	
Most of the time	28.0%	7	
Always	4.0%	1	
ar ar	nswered question	25	
	skipped question	1	

2. Getting paper-based documents in and out of the system is easy. Response Response **Answer Options** Count Percent 1 3.8% Never 19.2% 5 Sometimes Occasionally 19.2% 5 13 50.0% Most of the time 7.7% 2 Always answered question 26 skipped question 0

3. I sometimes wonder if I'm using the right command.			
Answer Options	Response Percent	Response Count	
Never	15.4%	4	
Sometimes	30.8%	8	
Occasionally	34.6%	9	
Most of the time	19.2%	5	
Always	0.0%	0	
answered question		26	
s	kipped question	0	

4. The speed of the EHR is fast enough to accomplish tasks.			
Answer Options	Response Percent	Response Count	
Agree	42.3%	11	
Disagree	53.8%	14	
Not Sure	3.8%	1	
an	swered question	26	
S	skipped question	0	

5. This software seems to disrupt the way I normally like to arrange my work.

Answer Options	Response Percent	Response Count
Agree	50.0%	13
Disagree	38.5%	10
Not Sure	11.5%	3
aı	nswered question	26
	skipped question	0

6. The organization of the menus or information lists seems quite logical.

Answer Options	Response Percent	Response Count
Agree	50.0%	13
Disagree	50.0%	13
Not Sure	0.0%	0
an	swered question	26
	skipped question	0

7. It is relatively easy to move from one part of a task to another.

Answer Options	Response Percent	Response Count
Agree	34.6%	9
Disagree	57.7%	15
Not Sure	7.7%	2
aı	nswered question	26
	skipped question	

8. It is easy to forget how to do things with the EHR.

Answer Options	Response Percent	Response Count
Agree	34.6%	9
Disagree	53.8%	14
Not Sure	11.5%	3
ar	swered question	26
	skipped question	0

9. The EHR occasionally performs in a way which can't be logically understood.

Answer Options	Response Percent	Response Count
True	69.2%	18
False	30.8%	8
ans	swered question	26
S	kipped question	0

10. I have to seek assistance most times when I use the EHR.		
Answer Options	Response Percent	Response Count
True	16.0% 84.0%	4 21
False	answered question	25
	skipped question	1

11. How often can you count on the EHR to be up and available. Answer Options Response

Answer Options	Percent	Count
Never	0.0%	0
Sometimes	3.8%	1
Occasionally	3.8%	1
Most of the time	73.1%	19
Always	19.2%	5
ans	swered question	26
Si	kipped question	0

12. How often is the EHR subject to frequent problems and crashes.

Answer Options	Response Percent	Response Count
Never	7.7%	2
Sometimes	23.1%	6
Occasionally	69.2%	18
Most of the time	0.0%	0
Always	0.0%	0
ans	swered question	26
s	kipped question	0

13. The EHR provides me with all the information I need to take care of the patient.

		•
Answer Options	Response Percent	Response Count
Never	0.0%	0
Sometimes	23.1%	6
Occasionally	7.7%	2
Most of the time	61.5%	16
Always	7.7%	2
ans	wered question	26
Si	kipped question	0

14. The EHR screens include a lot of extra information that I don't need.

Answer Options	Response Percent	Response Count
Agree	19.2%	5
Disagree	65.4%	17
Not Sure	15.4%	4
	answered question	26
	skipped question	0

15. There is inaccurate information in the EHR.

Answer Options	Response Percent	Response Count
Never	16.0%	4
Sometimes	64.0%	16
Occasionally	16.0%	4
Most of the time	4.0%	1
Always	0.0%	0
ans	swered question	25
S	kipped question	1

16. The EHR provides information that is up-to-date.

Answer Options	Response Percent	Respons Count		
Never	0.0%	0		
Sometimes	11.5%	3		
Occasionally	3.8%	1		
Most of the time	76.9%	20		
Always	7.7%	2		
ans	wered question		26	
Si	skipped question			

17. The system lets me quickly find the information I need.

Answer Options	Response Percent	Response Count
Never	0.0%	0
Sometimes	40.0%	10
Occasionally	28.0%	7
Most of the time	24.0%	6
Always	8.0%	2
ans	wered question	25
Si	kipped question	1

18. The information in the EHR is presented in a useful format.							
Answer Options Response Response Percent Count							
Yes	30.8%	8					
No	15.4%	4					
Depends on specific functionality	53.8%	14					
answered question							
skipped question							

19. The information in the system includes the level of detail that I need. Response Response **Answer Options** Percent Count 42.3% 11 Yes 15.4% 4 No Depends on specific functionality 42.3% 11 answered question 26 skipped question 0

20. Compared to previous routines, how has the EHR changed the performance of the following tasks?

Answer Options	Much More Difficult	Slightly More Difficult	No Change	Slightly Easier	Much Easier	N/A, Don't Know	Response Count
Documenting physical exams	3	6	1	1	4	11	26
Documenting histories	4	5	1	1	5	10	26
Documenting allergies	1	2	4	2	7	9	25
Documenting CPT and ICD-9 codes for billing purposes	2	0	3	3	4	14	26
Keeping problem lists updated	2	3	2	6	6	7	26
Keeping medication lists updated	3	4	3	2	6	8	26
Ordering laboratory and radiology tests	6	2	1	2	3	12	26
Reviewing laboratory and radiology results	2	2	3	5	7	7	26
Writing prescriptions	2	3	1	3	7	10	26
Renewing prescriptions	2	1	3	3	9	8	26
Monitoring medication safety during prescribing	1	1	1	5	4	14	26
Monitoring patient medication adherence	1	0	4	2	3	16	26
Communicating referral information to specialists	2	0	4	7	2	11	26
Reviewing referral information from specialists	1	1	9	5	2	8	26
Ordering appropriate preventive care services	1	4	3	3	2	13	26
Making a list of patients based on diagnosis or history	1	0	0	3	1	21	26
Contacting patients to remind them of appointments	0	0	4	2	2	18	26
Assisting patients in self-management activities	1	1	2	2	2	18	26
<u>. </u>					answe	red question	26

21. How strongly do you agree or disagree with the following statements regarding the EHR?

Answer Options	Completely Agree	Generally Agree	Generally Disagree	Completely Disagree	Don't Know	N/A	Response Count
Using the EHR has enabled me to accomplish tasks quicker	2	11	9	4	0	0	26
I work longer hours to see the same number of patients	8	4	4	4	2	4	26
Using the EHR has enhanced my effectiveness in my job	2	12	8	4	0	0	26
Using the EHR has made it easier to do my job	3	11	8	4	0	0	26
I find the EHR useful in my job	2	16	5	2	1	0	26
Learning to operate the EHR has been easy for me	1	15	8	2	0	0	26
I have become skilled at using the advanced features	2	12	5	0	4	3	26
Easier to access patient information from outside the office	2	5	1	0	3	15	26
There are too many alerts and reminders	3	7	3	1	4	8	26
Has decreased the amount of time I spend talking to patients	4	6	7	2	3	4	26
Helps me adhere to clinical practice guidelines	1	7	2	0	6	10	26
Using an EHR has caused disruptions to my work flow	4	8	8	3	1	2	26
Has improved my ability to make decisions about patient care	1	6	4	1	3	10	25
Has improved my ability to provide preventive care	1	6	3	2	4	10	26
I can better monitor how many of my patients are receiving appropriate care	1	4	5	1	2	13	26
Benefits of adopting an EHR have outweighed the challenges	2	10	5	3	4	2	26
				ans	swered qu	estion	26

22. Would you recommend EHRs to other providers interested in adopting health information technology?

Answer Options	Response Percent	Response Count
Yes	72.0%	18
No	28.0%	7
	answered question	25
	skipped question	1

23. If you could change one thing about the Allscripts EHR system, what would it be?

Answer Options	Response Count
	18
answered question	18
skipped question	8

24. What has been the most positive benefit of using an EHR?

Answer Options	Response Count
	18
answered questio	<i>n</i> 18
skipped auestio	n 8

25. How often do you print out a Visit Summary report from the EHR system for your patient at the conclusion of the patient visit?

Answer Options	Response Percent	Response Count
Always	0.0%	0
Sometimes	20.0%	5
Never	44.0%	11
Don't know	12.0%	3
Not Applicable	24.0%	6
ans	swered question	25
S	kipped question	1

26. How long have you been using the Allscripts EHR at your practice?

Answer Options	Response Count
	26
answered question	26
skipped question	0

27. How would you classify your level of comfort with general computer technology (e.g. email, Internet, word processing)?

Answer Options	Response Percent	Response Count
Very comfortable	53.8%	14
Somewhat comfortable	46.2%	12
Not very comfortable	0.0%	0
ans	wered question	26
Si	kipped question	0

28. Please choose the statement that best describes the training you received for your current EHR.

Answer Options	Response Percent	Response Count
I have received no training and I'm learning the system as I use it	0.0%	0
Informal training by practice staff when time permitted	3.8%	1
Less than ten hours dedicated to formal training (with vendor or practice trainers)	53.8%	14
Ten or more hours dedicated to formal training (with vendor or practice trainers)	42.3%	11
ans	wered question	26
SA	kipped question	0

29. What is your title?

Answer Options	Response Percent	Response Count
Clerical	37.5%	9
Nurse	33.3%	8
Office Manager	4.2%	1
Physician	8.3%	2
Physician Assistant	0.0%	0
Other	16.7%	4
ans	swered question	24
S	kipped auestion	2

30. Do you have any previous EHR experience?

Answer Options	Response Percent	Response Count
Yes	26.9%	7
No	73.1%	19
	answered question	26
	skipped question	0

31. How satisfied are you with the EHR system?			
Answer Options	Response Percent	Response Count	
Very Dissatisfied	11.5%	3	
Dissatisfied	23.1%	6	
Neutral	30.8%	8	
Somewhat Satisfied	30.8%	8	
Very Satisfied	3.8%	1	
ans	wered question	26	
SI	kipped question	0	

32. Please provide additional comments as needed.		
Answer Options	Response Count	
	6	
answered question	6	
skipped question	20	

John Hargreaves

From: Brosch, Laura R Dr CIV USA MEDCOM USAMRMC [Laura.Brosch@us.army.mil]

Sent: Thursday, April 19, 2012 2:16 PM

To: Brian Lieb

Richard Wozniak; Bennett, Jodi H Ms CIV USA MEDCOM USAMRMC; 'Stephenson, Jeffrey Dr IBA'; 'betty.levine@tatrc.org'; Bane, Elena G Ms CIV USA MEDCOM USAMRAA; John Hargreaves; Duchesneau, Caryn L Ms CIV USA MEDCOM Cc:

USAMRMC; Katopol, Kristen R Ms CTR US USA MEDCOM USAMRMC; Englar, Nancy E CTR US USA MEDCOM USAMRMC; Drayton, Maria Ms CTR US USA MEDCOM USAMRMC; Brosch, Laura R Dr CIV USA MEDCOM USAMRMC

Subject: A-15835.2, Protocol Closure Memorandum (Proposal Log Number 09064002, Award Number W81XWH-09-2-0061)

(UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

SUBJECT: Project Completion for the Protocol, "Military Interoperable Digital Hospital Testbed (MIDHT) Year 2 Arm 1: Longitudinal Study for the Use of Ambulatory Electronic Health Records (EHR) in Rural Communities," Submitted by Brian Lieb, DO, Conemaugh Valley Memorial Hospital, Carrolltown, Pennsylvania, in Support of the Proposal, "Military Interoperable Digital Hospital Testbed (MIDHT), Submitted by Richard S. Wozniak, MD, Memorial Medical Center, Johnstown, Pennsylvania, Proposal Log Number 09064002, Award Number W81XWH-09-2-0061, HRPO Log Number A-15835.2

- A final report was received by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) on 12 April 2012. This no greater than minimal risk study was initially approved by the HRPO on 18 May 2010.
- 2. The Conemaugh Memorial Medical Center Institutional Review Board documentation acknowledging closure of this protocol, dated 2 April 2012, was received by the USAMRMC ORP HRPO on 12 April 2012. The final report and supporting documents were reviewed and found to be acceptable.
- No further review of the protocol will be conducted, and the HRPO protocol file will be closed.
- The HRPO point of contact for this study is Nancy Englar, MHL, BSN, RN, Human Subjects Protection Scientist, 301-619-2242/nancy.e.englar.ctr@us.army.mil.

LAURA R. BROSCH, PhD Director, Office of Research Protections Director, Human Research Protection Office U.S. Army Medical Research and Materiel Command

Note: The official copy of this closure memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.

Classification: UNCLASSIFIED

Caveats: NONE

6/19/2012

Appendix 3 – Protocol Closure Memorandum

Page 1 of 1

John Hargreaves

Duchesneau, Caryn L Ms CIV USA MEDCOM USAMRMC [Caryn.Duchesneau@us.army.mil] From:

Monday, August 29, 2011 5:03 PM Sent:

To:

John Hargreaves; Bennett, Jodi H Ms CIV USA MEDCOM USAMRMC; John Karduck; 'Stephenson, Jeffrey Dr IBA'; Jeanette Cc:

Croner; Chris Smith; Thomas Simunich; Wendi Nagle; Bane, Elena G Ms CIV USA MEDCOM USAMRAA; 'steve.steffensen@tatrc.org'; Brosch, Laura R Dr CIV USA MEDCOM USAMRMC; Duchesneau, Caryn L Ms CIV USA MEDCOM USAMRMC; Katopol, Kristen R Ms CTR US USA MEDCOM USAMRMC; Eaton, Karen M Ms CTR US USA MEDCOM USAMRMC; Drayton, Maria Ms CTR US USA MEDCOM USAMRMC; Dyson, Nicole CIV US USA MEDCOM

Subject: A-16192.1, Protocol Closure Memorandum (Proposal Log Number 10322003, Award Number W81XWH-10-2-0180)

(UNCLASSIFIED)

Classification: <u>UNCLASSIFIED</u> Caveats: NONE

SUBJECT: Project Completion for the Protocol, "Military Interoperable Digital Hospital Testbed (MIDHT) Year 2, Arm System-Wide Image Access: Analysis on Duplicate Testing in a Rural Healthcare Environment," Submitted by Richard S. Wozniak, MD, Memorial Medical Center, Johnstown, Pennsylvania, in Support of the Proposal, "Military Interoperable Digital Hospital Testbed (MIDHT)," Submitted by John Karduck, MD, Memorial Medical Center, Johnstown, Pennsylvania, Proposal Log Number 10322003, Award Number W81XWH-10-2-0180, HRPO Log Number A-16192.1

- A final report and request to close the protocol was received by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections, Human Research Protection Office (HRPO) on 27 July 2011. This no greater than minimal risk study was initially approved by the HRPO on 18 August 2010.
- The Memorial Medical Center Institutional Review Board documentation acknowledging closure of this protocol, dated 14 July 2011, was received by the USAMRMC HRPO on 27 July 2011. The final report and supporting documents were reviewed and found to be acceptable.
- No further review of the protocol will be conducted, and the HRPO protocol file will be closed.
- The HRPO point of contact for this study is Karen M. Eaton, MS, Human Subjects Protection Scientist, at 301-619-9268/karen.m.eaton@us.army.mil.

CARYN L. DUCHESNEAU, CIP Chief, Human Subjects Protection Review Human Research Protection Office Office of Research Protections U.S. Army Medical Research and Materiel Command

Note: The official copy of this closure memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.

Classification: UNCLASSIFIED

Caveats: NONE

8/30/2011

Appendix 4 – PACS Study Manuscript

Full Title Page

Richard S. Wozniak, MD, John S. Hargreaves, MBA, Thomas J. Simunich, MBA, MS in MIS, Lisa Pasierb, Ph.D, Jeanette R. Croner, MHA.

Conemaugh Memorial Medical Center 1086 Franklin Street Johnstown, Pennsylvania 15905

RW – <u>rwozniak@conemaugh.org</u>, 814-534-9106

JH – <u>jhargrea@conemaugh.org</u>, 814-269-5277

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LP – <u>lpasierb@conemaugh.org</u>, 814-269-5248

JC – <u>jcroner@conemaugh.org</u>, 814-269-5247

The Impact of System-Wide Image Access on Duplicate Testing in a Rural Healthcare System.

This paper has not been presented at an RSNA meeting and has not been accepted for presentation at a future meeting.

Type of manuscript: Original Research

Word Count: 2,088

Address for Correspondence: Richard Wozniak, MD

Conemaugh Memorial Medical Center

1086 Franklin Street Johnstown, PA 15905

Funding: This work was supported by the U.S. Army Medical Research and Materiel Command under Contract No. W81XWH-09-2-0061.

Abbreviated Title Page

- a) The Impact of System-Wide Image Access on Duplicate Testing in a Rural Healthcare System.
- b) Original Research
- c) Advance in Knowledge
 - 1. The ability for the receiving institution to view images taken off-site through a picture archiving and communications system (PACS) resulted in a 7% reduction in duplicate chest x-ray and CT scan (head) testing from 0-7 days when compared to a pre PACS implementation period.
 - 2. As surveyed, seventy percent of physicians positively stated that immediate image access did reduce the number of exams reordered.

d) Implications for Patient Care

- 1. System-wide availability of images will have a positive impact and may reduce unnecessary imaging at the receiving institution. Benefits will also transfer to patients as health risks associated with radiation exposure will decrease.
- 2. Implementers should have a solid plan in place to communicate and train users on the new functionality. Leadership should expect that change management will vary amongst physicians and may impact immediate results.

e) Summary Statement

The implementation of picture archiving and communications system (PACS) throughout a rural health care system will have positive benefits both to patients and the institutions involved and likely reduce unnecessary imaging, operating costs and radiation exposure to patients.

Abstract

Purpose:

To test the hypothesis that duplicate imaging will decrease among transfer patients to a tertiary care center from two rural off-site hospitals after the implementation of picture archive and communications system (PACS) at the off-sites.

Materials and Methods:

This minimal risk, HIPAA-compliant study was approved by Conemaugh's Institutional Review Board (IRB), with waiver for informed consent for retrospective review of medical records. Using a master patient index (MPI), 625 duplicate chest x-rays and CT scans of the head between sending and receiving institution (taken within 0-7 days) were collected from July 2008 to June 2010. The study design utilized a pre vs. post quantitative methodology, with time periods based upon the extension of PACS technology to off-site locations. Additionally, qualitative feedback was gathered from physicians (n=76) using a survey tool to assess the impact of immediate image access and to quantify the number of off-site studies viewed by physicians (n=70) with PACS access.

Results:

A Chi-Square test of independence applied to either Days between date of service or Aggregated Days between date of service over time period did not yield a statistically significant result despite a 7% reduction in duplicate imaging (hypothesis not accepted). A financial analysis of the resulting seven percent reduction in duplicate tests suggests a savings of \$187,075 to patients and/or insurance companies.

Conclusion:

Extension of PACS technology to referring institutions is beneficial; however, realization of a significant reduction in duplicate testing will depend upon full support of ordering physicians, proper training, and effective communication.

Introduction

The United States spends more on health care than any other country with an annual average of \$6,401 per person, which is 2.4 times the average of developed countries (1). As hospital reimbursement becomes more challenging, health information technology (HIT) may offer solutions to achieve organization-wide cost savings. Duplicate testing is not only a well-known source of extraneous health care expenses but may also pose additional radiation risks to patients. As a rural health care system with multiple referring hospitals, how can efficiency and patient safety improve through coordinated care?

Duplicate testing remains an industry-wide challenge that must be addressed in order for health care reform to be realized. Haley et al found that 53% of transferred trauma patients had some portion of their images duplicated; resulting in \$650,000 in additional costs (2). Thomas et al presented similar findings in that 43% of patients had computed topography (CT) scans repeated during facility transfers (3).

Recent studies have stressed the inherent risk to patients due to increased source of radiation exposure. Brenner and Hall state that 62 million CT scans are performed annually in the United States and involve larger radiation doses than more conventional x-ray tests (4). Berrington de Gonzalez et al also provide support for increased cancer risk estimating that 29,000 future cancers could be related to CT scans (5). Sodickson et al recommend the quantity of imaging should be monitored over time to ensure minimization of radiation exposure (6).

One solution that may reduce unnecessary radiology testing and reduce radiation exposure between central and remote sites is called Picture Archiving and Communication System (PACS). PACS are computer networks dedicated to the storage, retrieval, and presentation of images produced by medical imaging devices. PACS replaces film archives, allowing imaging access simultaneously and from off-site locations. PACS is commonly believed to reduce the number of unnecessary duplicate imaging tests ordered because of originals being lost or stored at a remote location. Past research suggests an individualized evaluation of PACS technology where incidence of duplicate testing may be high (7). Institutions involved with the transfer of patients may have the most to gain through this process.

Materials & Methods

This study, located within the Conemaugh Health System (CHS), analyzed the impact of extending PACS to two remote hospitals stretched over a two county area in southwestern Pennsylvania. Conemaugh Memorial Medical Center (central site), located in Johnstown, Pennsylvania, is a tertiary care regional referral hospital known for clinical excellence and patient satisfaction. The level 1 trauma center located at the central site is one of just eleven centers in Pennsylvania. Miners Medical Center (remote site 1) is a 30-bed community satellite hospital located 45 minutes to the north of Johnstown whereas Meyersdale Medical Center (remote site 2) is a 20-bed Critical Care Access hospital located 60 minutes to the south of Johnstown. The study was approved by Conemaugh's Institutional Review Board (IRB), which included a waiver of informed consent for retrospective review of medical records and a minimal risk designation.

Implementation

Conemaugh extended the McKesson PACS, Radiology Information System (RIS) and Dolby Digital Dictation system used at the central site to the two remote facilities (Figure 1). This project allowed CHS to achieve consistency of radiology imaging, report management, and image access across the health system. PACS went live at the remote sites on July 1, 2009 (image transfer only). During the next six months, activities were completed to seamlessly integrate both the RIS and PACS systems for sharing of reports in production use.

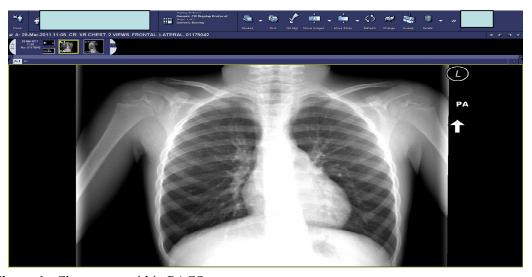


Figure 1. Chest x-ray within PACS.

Study Design

Both qualitative and quantitative methods were employed to investigate the study objectives and the hypothesis. Researchers hypothesized that the number of duplicated chest X-rays and CT scans (head) would significantly decrease after implementation of each phase of the PACS implementation compared to that of baseline.

Data collection primarily utilized historical data (retrospectively) to obtain the number of duplicated diagnostic imaging tests by evaluating empirical data retrieved from hospital financial systems. The data was limited to patients that were first treated at one of the two remote sites and subsequently treated at the central site within the defined duplicate test time frame (0-7 days). This comparative analysis used a PRE (before PACS) and POST (after PACS) time period, see Table I, design to ascertain the expected change in the viewing of PACS images. The time periods were chosen with consideration for symmetry of data sets, stabilization of implementation, and the possibility of seasonality (time) as a covariate.

P R E (baseline)		POST	
2	(basefine)	Phase 1	Phase 2
2008	200	09	2010
July through December	January through June	July through December	January through June

Table I. Study Timeline.

Conemaugh MIS department provided duplicate test reports to the study team for analysis using the Master Patient Index (MPI) software. The report included chest x-rays (CPT 71010 and 71020) and CT scans of the head (CPT 70450) for the stated time periods. The report included data for patients that had the same test, as specified by the CPT codes above, and determined by the patient identifier, date of service, and service location. Inclusion of data was limited to studies repeated at the central site within 0-7 days. Time of service was used to include/exclude tests performed on the same date. Additional images completed at CMMC were removed from the analysis. Summary radiology volume data was also collected to assess the level of

consistency of volume over time and thereby providing one measure of the homogeneity of the pre and post data sets.

In order to understand actual CMMC physician usage of studies performed at the two rural hospitals, PACS User Reports were provided to the study team for analysis. The population included a randomized, proportionate sample of active physicians on the CMMC medical staff. Reports were prepared for October - December 2009 and April - June 2010, which detailed viewing of studies that originated from the remote sites.

A physician opinion survey was also distributed to all applicable physicians on the CMMC medical staff in traditional hard copy and online form. The survey was designed by Canada Health Infoway and was modified for use by Conemaugh with permission. The survey was designed to gather qualitative feedback from physicians that use the system daily in their course of patient care. Survey objectives included assessing the impact of immediate image access to studies performed at two rural hospitals on productivity, decision-making, patient transfers, and duplicated exams.

Results

A Chi-Square test of independence applied to either Days between (b/w) date of service (DOS) or Aggregated Days b/w DOS over time period does not yield a statistically significant result despite a 7% reduction in duplicate imaging (hypothesis not accepted). However, a Chi-Square test of goodness-of-fit for aggregated Days b/w DOS using pre data as the expected (population) values and the post data as observed values does yield a statistically significant result at a family-wise alpha = 0.05. This result implies that the implementation of the PACS system at the remote

sites did contribute to the change in the distribution of the count of duplicative testing (Figure 2).

Furthermore, no statistical significance was found by CPT code or location (Figures 3-4).

Radiology volume data by CPT code for the remote sites is homogeneous between the pre and post data sets.

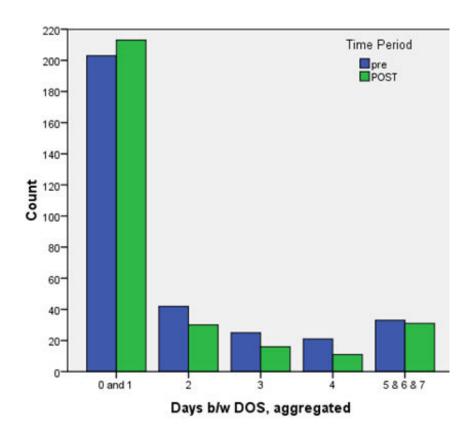


Figure 2. Duplicated Tests (PRE vs. POST) by Days Between Date of Service.

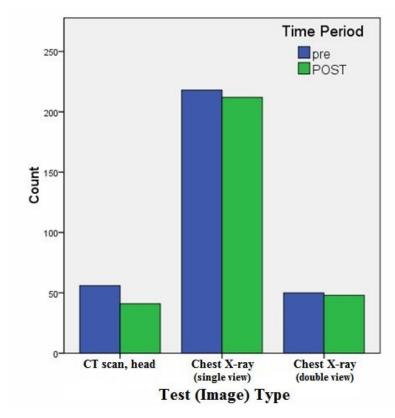


Figure 3. Duplicated Tests (PRE vs. POST) by CPT Code.

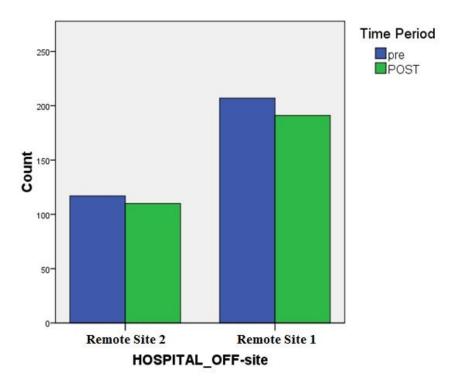


Figure 4. Duplicated Tests (PRE vs. POST) by Initial Location.

Despite non-significant findings in the reduction of duplicate testing, the financial analysis of the resulting seven percent reduction in duplicated chest x-rays and CT scans of the head suggests a savings of \$187,075 to patients and/or insurance companies. As healthcare costs continue to climb and funding becomes more restricted, hospitals and health systems must consider implementing health information technologies to improve efficiencies and save money. Though not specifically addressed in this study, the reduction in duplicate testing will translate into less radiation exposure opportunities for patients transferred between facilities.

The following data was collected for a randomized, proportionate sample of 70 physicians with PACS access. As depicted below in Figure 5, the most active users of the PACS system in terms of viewing studies originating from MIMC and MYMC are Emergency Medicine (n=65) and Trauma (n=51) physicians. This result is expected as CMMC is a tertiary care referral hospital with a Level 1 trauma center. The next grouping includes Otolaryngology (n=35), Urology (n=34), and Pulmonary (n=31). A third grouping includes General Surgery (n=28), Orthopedics (n=27) and Neurosurgery (n=26). The graph does not include an outlier for an orthopedic surgeon (n=581).

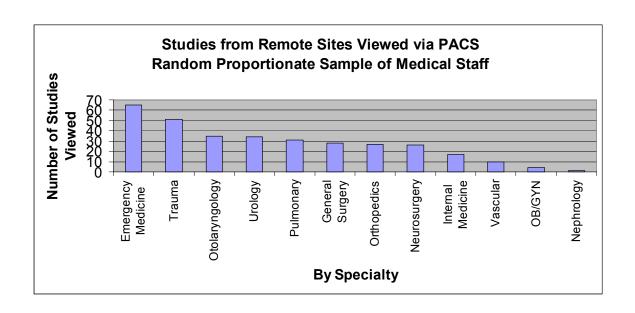


Figure 5. Number of studies performed off-site viewed using PACS.

Qualitative feedback from system users was collected via a survey tool. Seventy six physicians completed the survey during October 2010 through January 2011, representing approximately a 37% response rate. The following graph depicts self reported frequency of electronic access (Frequently, Sometimes, Seldom, or Never) of images originating from MIMC and MYMC by stated specialty. Results do align with empirical usage data for highest volume specialties: General Surgery, Trauma, Emergency Medicine, Internal Medicine, Orthopedics, Urology (not shown), Neurosurgery, Otolaryngology (not shown), and Pulmonary (not shown). Family practitioners responded the most but actual usage of the system is limited.

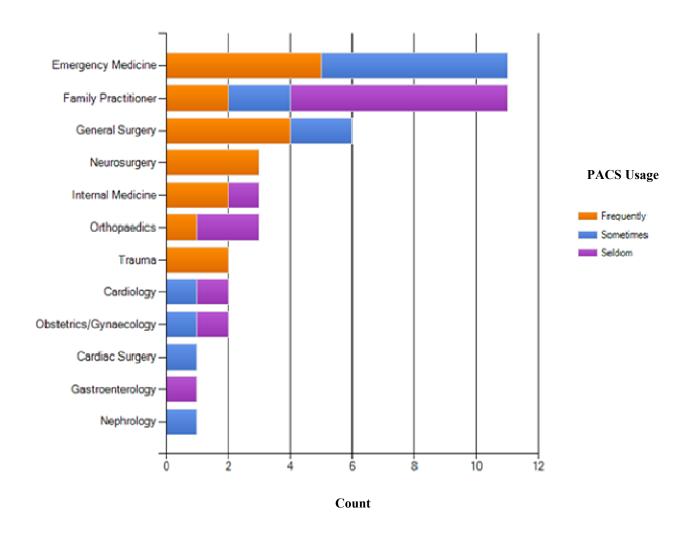


Figure 6. Survey Respondents by Specialty and Frequency of PACS Usage.

Surveys that indicated that the physician never used PACS to access images from the remote sites were removed from the dataset before analysis. The remaining responses (n=55) formed the dataset of analysis.

The most important survey question in terms of the hypothesis was Question 10a: Immediate PACS image access to films performed at Miners/Meyersdale has reduced the number of exams reordered because the images were not available when I needed them? Seventy percent (70%) of physicians that use the PACS system for this purpose either Strongly Agreed or Moderately

Agreed that the number of duplicated tests has been reduced post implementation whereas the remaining 30% disagreed or stated it was not applicable.

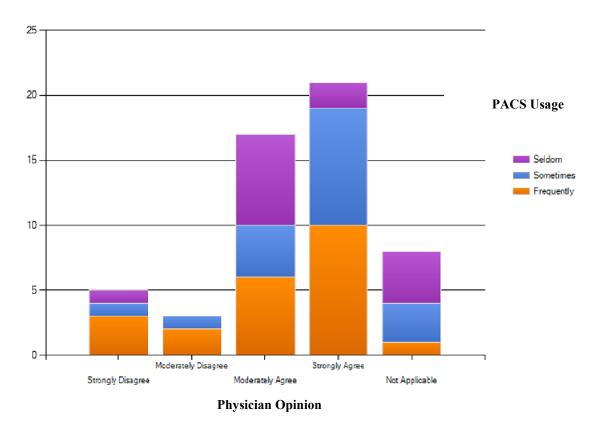


Figure 7. Self-reported Physician Opinion on Duplicate Testing by Frequency of PACS Usage.

Hypothesis testing of this question and others indicate that the response per category most probably represents a real difference in respondent opinion. The results of the hypothesis testing do not change for the aggregations of the responses of those questions. [Asymptotic significance at the 0.05 level is shown for all hypothesis testing.] Questions were analyzed using the original scale, a 5 level Likert scale, and an aggregation (collapsing) of that scale comprised of 3 levels (Agree, Disagree, N/A).

Discussion

The implementation of PACS technology at smaller hospitals within the same health system is beneficial and likely to reduce costs and radiation exposure to patients. This study found that positive qualitative feedback and modest system usage by physicians did translate into a reduction in duplicate testing although not significant for patients receiving care from multiple facilities within the same rural health system. Despite new technologies being available, physicians must take the appropriate amount of time to receive education and attend training sessions. Unfortunately, some physicians may not change their ordering habits, which will reduce the expected benefit significantly depending on position and corresponding volume.

One limitation of the study is that the reason for ordering the test was not consistently collected and therefore unavailable for analysis by investigators. Such analysis would have been beneficial to determine how many more duplicate tests could have been prevented if the physician had been aware of the previous test conducted off-site or the test was re-ordered based upon sound clinical judgment.

To enhance data analysis and study conclusions, future research should attempt to collect reasoning information used in deciding to reorder an image. Given the surge in new technology investments nationwide from American Recovery and Reinvestment Act (ARRA) funding, future studies should be conducted on health information exchanges (HIE) that share images across the street or across state lines. An understanding of the cost benefit analysis of said HIE projects will be important to move the industry forward.

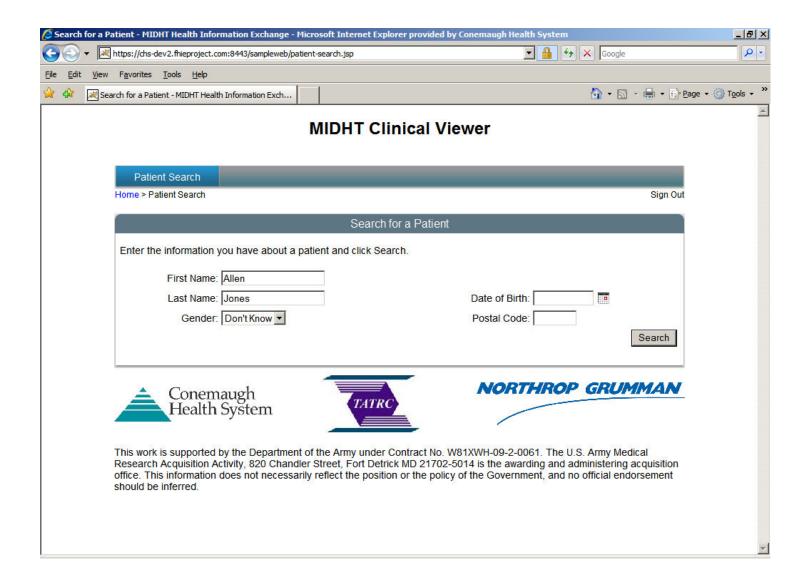
Acknowledgments

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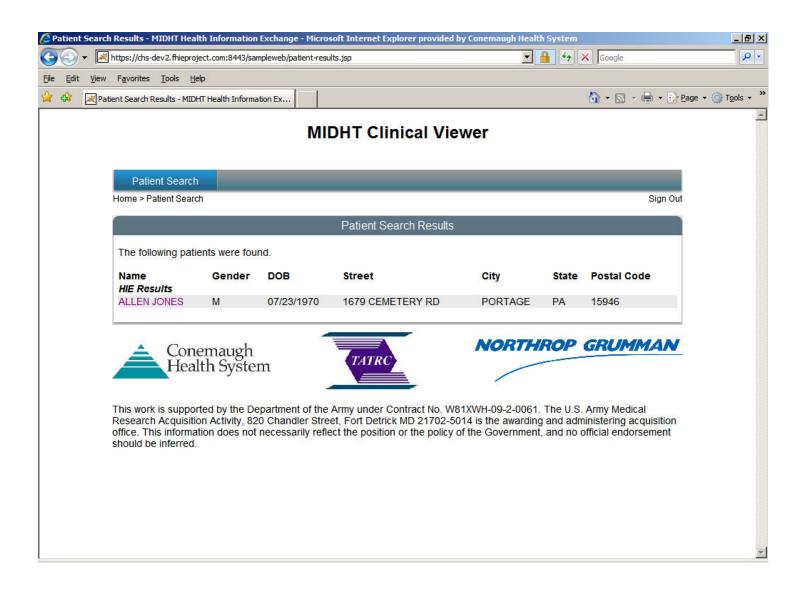
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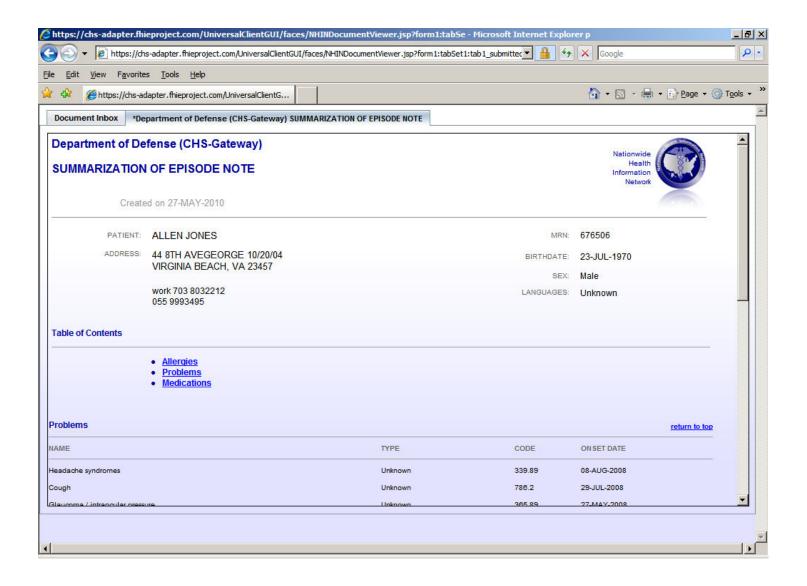
Appendix 5 - MIDHT Clinical Viewer - Patient Search



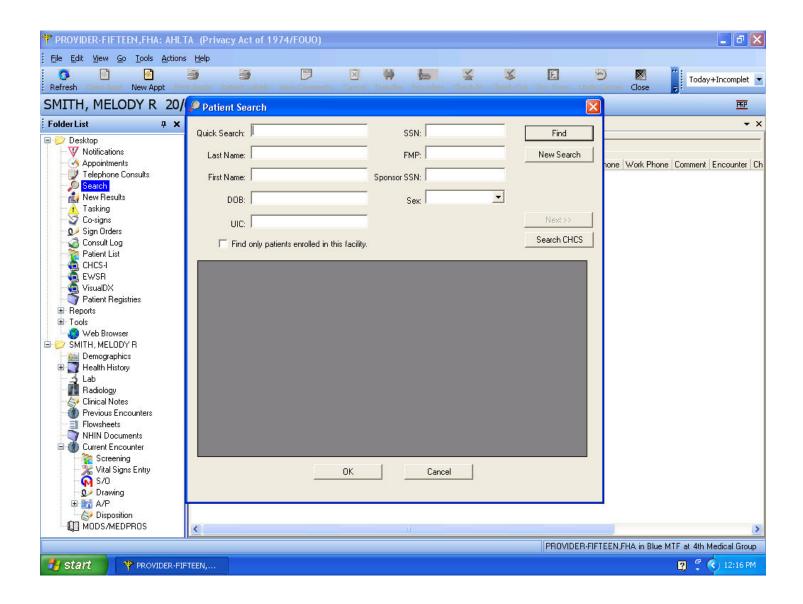
MIDHT Clinical Viewer - Patient found utilizing Initiate EMPI web service



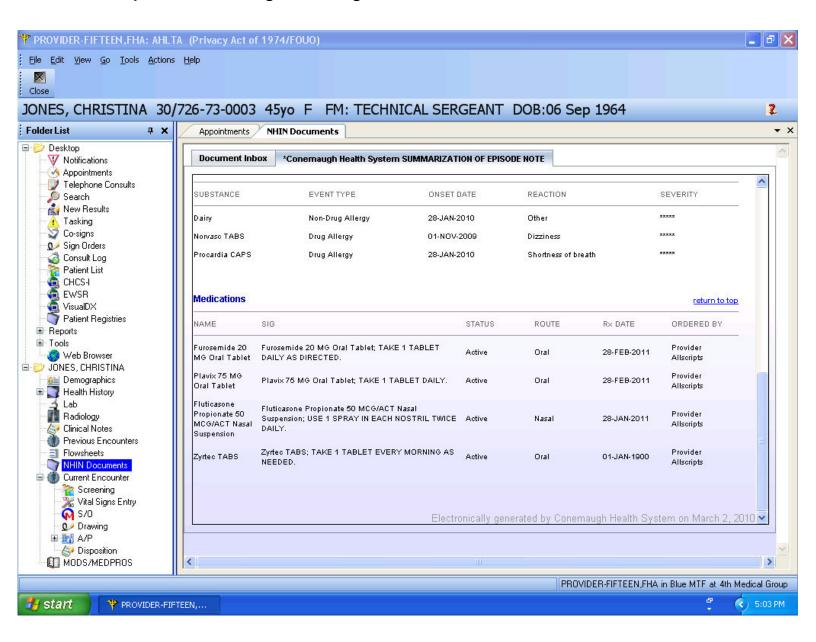
Conemaugh provider retrieving DoD (AHLTA) data from "Document Inbox"



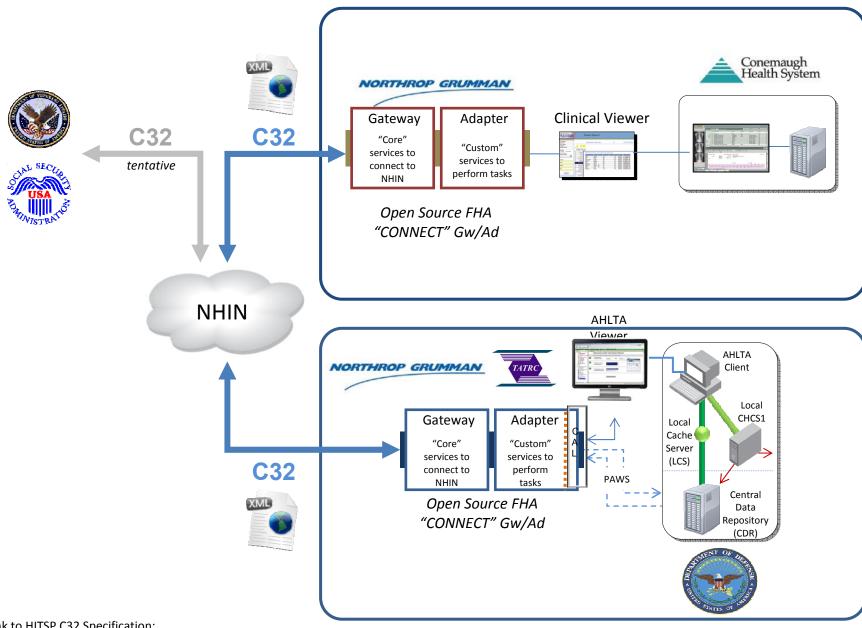
DoD provider searching for patient - AHLTA Client (test)



DoD provider retrieving Conemaugh data from "NHIN Documents" folder



Appendix 6 - Health Information Exchange Architecture



Link to HITSP C32 Specification:

http://www.hitsp.org/ConstructSet Details.aspx?&PrefixAlpha=4&PrefixNumeric=32